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(71) Applicant *(for all designated States except US)*: **HOME-MEDICINE (USA), INC.** [US/US]; c/o Pepper Hamilton LLP, 1201 Market Street, Suite 1600, Wilmington, DE 19801 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SAREL, Oded** [IL/IL]; Tel-Zur Street 37, 40 500 Even Yehuda (IL).

(74) Agent: **G. E. EHRLICH (1995) LTD.**; Bezalel Street 28, 52 521 Ramat Gan (IL).

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(54) Title: PARAMETER SENSING AND EVALUATION SYSTEM

(57) Abstract: A parameter evaluation system comprising a boundary input device for setting boundaries in a variation range of one or more parameters, thereby to define regions within said variation range, a label input device for associating labels with said regions, a rule input device for setting rules to associate at least one of a plurality of output recommendations with each of said regions and with combinations thereof and an output device to present a user with an output recommendation associated with a region or combination thereof corresponding to at least one measured parameter input to said system. The input device is a parameter value region selection and categorization input device for setting boundaries in the variation range of the parameter, defining regions therebetween and categorizing the regions. The device comprises a visual representation of the variation range as a linear continuum, a continuum divider for visually dividing the continuum at user selectable points therealong, the points corresponding to values of the parameter, thereby to define regions therebetween and a category definer for defining categories for association with the regions. The device has an application in a patient monitoring kit under remote supervision of a physician.

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Parameter Sensing and Evaluation System

Field of the Invention

The present invention relates to a parameter sensing and evaluation system and more particularly but not exclusively to a parameter sensing and evaluation system for use in the medical field.

Background of the Invention

There exist in the patent literature various proposals for medical sensing and evaluation over computer networks. The following U.S. Patents are believed to represent the state of the art: 5,907,291; 5,906,208; 5,902,234; 5,897,493; 5,895,354; 5,892,570; 5,879,292; 5,873,369; 5,868,669; 5,868,135; 5,868,134; 5,865,733; 5,855,550; 5,848,975; 5,842,977; 5,842,975; 5,840,018; 5,827,180; 5,811,681; 5,791,908; 5,791,342; 5,769,074; 5,758,652; 5,677,979; 5,619,991.

In the medical parameter evaluation field, there are a number of expert systems that use preset rules to make medical diagnoses and like decisions. Generally, their use has not been accepted by physicians because they are not trusted to make reliable decisions. The physician or other care provider is generally uncomfortable with being unable to see all stages of the decision-making process.

Nevertheless, some form of automation that allows a patient requiring continuing supervision a degree of independence is desirable. For example, a patient may require monitoring of his blood pressure and other parameters whilst undergoing a course of treatment. Certain fluctuations and trends in his blood pressure level may be of considerable interest to his physician but it is not desirable that the patient should contact the physician or other care provider on a highly frequent basis and it is not always practical to provide the patient with a full set of rules for events that should be reported, especially when multiple parameters are involved. It is likewise not always

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practical to ask a patient to keep records of the monitoring results that could reveal important trends.

Summary of the Invention

Embodiments of the present invention overcome the drawbacks of the prior art by firstly permitting the physician or other care provider to set the scoring rules per each single parameter and the rules for aggregation of parameters independently per patient, and secondly by ensuring that dangerous levels in one parameter cannot be masked by opposite changes in another parameter.

Embodiments of the present invention also seek to provide a highly effective computer network based system for medical sensing and evaluation as well as interface elements useful in the system.

Further embodiments of the invention disclose a medical condition sensing system including a multiplicity of general purpose computers disposed in user locations. The computers are connected via a computer network to a controller computer remote from the user locations. Personal parameter measuring software is resident at the user location and the controller computer for measuring a personal parameter of a user, such as heart rate, blood pressure etc. Parameter reference levels are set and the controller computer compares a currently measured personal parameter with a corresponding reference and provides a comparison output. In essence the system awards points for levels of an individual personal parameter measured and decides to take action after a given number of points have been exceeded, the given number being set per user to take into account the parameters being measured and the condition being considered.

The above-described embodiment preferably provides the physician or other care provider with a system that allows a patient to carry out self-monitoring at home, and at the same time ensures that the physician or other care provider will be informed promptly if a certain points threshold is reached.

The above-described system, may make decisions on a summation basis. Alternatively it may make decisions in accordance with the parameter evaluation system described below in the second to seventh aspects of the present invention described below.

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There is thus provided in accordance with a first aspect of the present invention a medical condition sensing system including a multiplicity of general purpose computers disposed in user locations and being connected via a computer network to at least one controller computer remote from at least one of the user locations, personal parameter measuring software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for measuring at least one personal parameter of at least one user, personal parameter reference generating software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for establishing a reference for the at least one personal parameter, and personal parameter comparison software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for comparing at least one currently measured personal parameter with a corresponding reference and providing a comparison output.

Further in accordance with a preferred embodiment of the present invention the medical condition sensing system also includes alert indication software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for providing a generally real time alert indication to the user based at least partially on the comparison output. Preferably, the alert indication software is resident on the multiplicity of general purpose computers.

Still further in accordance with a preferred embodiment of the present invention the reference may be a personal parameter baseline constructed from pre-real time measurements of the personal parameter, a calibration reference employing a measurement of a personal parameter based on a calibration input, a calibration reference based on a calibration input, a calibration reference based on a calibration input supplied from another computer via the computer network, and/or a calibration reference employing a measurement of a personal parameter based on a calibration input supplied from another computer via the computer network. Preferably, the personal parameter comparison software is operative to compare at least one currently measured personal parameter with the calibration reference.

Additionally in accordance with a preferred embodiment of the present invention, the medical condition sensing system also includes notification software

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resident on at least one of the multiplicity of general purpose computers and the at least one controller for transmitting a notification from one of the at multiplicity of general purpose computers to at least one other computer based on the comparison output.

Further in accordance with a preferred embodiment of the present invention, the personal parameter includes a heart function parameter, a blood parameter, a electrocardiogram parameter, a hearing function parameter, a skin appearance parameter, a tissue appearance parameter, an optically sensible parameter, an electrically sensible parameter, a thermally sensible parameter, an audibly sensible parameter, and/or a chemically sensible parameter.

Still further in accordance with a preferred embodiment of the present invention the personal parameter comparison software is operative to compare optical images of at least one body region.

Additionally in accordance with a preferred embodiment of the present invention the personal parameter measuring software is operative to measure at least one personal parameter of at least one user in response to an input supplied to the user. The personal parameter measuring software also includes feedback software and feedback circuitry for calibrating the input supplied to the user. Preferably, the feedback software is operative to communicate between a general-purpose computer and the controller computer over the computer network.

Additionally or alternatively the feedback circuitry is operative to communicate between a general purpose computer and the controller computer over the computer network.

Still further in accordance with a preferred embodiment of the present invention the personal parameter measuring software also includes feedback software for calibrating a measured personal parameter of a user.

Furthermore in accordance with a preferred embodiment of the present invention the medical condition sensing system also includes feedback circuitry for calibrating a measured personal parameter of a user. Additionally or alternatively the feedback software is operative to communicate between a general purpose computer and the controller computer over the computer network.

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Moreover the feedback circuitry is operative to communicate between a general purpose computer and the controller computer over the computer network.

Further in accordance with a preferred embodiment of the present invention the medical condition sensing system also includes software utilizing the output of at least one of the personal parameter measuring software, the personal parameter reference generating software, and the personal parameter comparison software for providing at least one of recommendations and indications to a user.

Still further in accordance with a preferred embodiment of the present invention the medical condition sensing system also includes a manned center accessible at least via the computer network for receiving at least some of the output of at least one of the personal parameter measuring software, the personal parameter reference generating software the personal parameter comparison software and at least one of recommendations and indications to a user and providing health professional interaction with the user.

Preferably, the manned center is accessible at least via the computer network for receiving at least some of the output of at least one of the personal parameter measuring software, the personal parameter reference generating software the personal parameter comparison software and at least one of recommendations and indications to a user and providing health professional interaction with the user.

Additionally or preferably at least one of the recommendations and indications as well as the criteria therefor is determinable by a user's health professional by transmitting instructions to at least one of the controller computer and the general purpose computer via the computer network. Furthermore, at least one of the recommendations and indications as well as the criteria therefor is determinable by a user's health professional by transmitting instructions to at least one of the controller computer and the general purpose computer via the computer network.

Still further in accordance with a preferred embodiment of the present invention the manned center employs a personal physician of the user and communicates with him via through at least one of telephone and data links via at least one of wired and wireless communication media.

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Moreover in accordance with a preferred embodiment of the present invention, the medical condition sensing system also includes personal parameter analysis software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for analyzing the at least one personal parameter of at least one user. The analysis of at least one personal parameter of at least one user takes place partially at a general purpose computer at at least one user location and partially at the at least one controller computer.

Additionally or alternatively the analysis of at least one personal parameter of at least one user at a general purpose computer at at least one user location provides an analysis output which determines whether further analysis of the at least one personal parameter is carried out at the at least one controller computer.

Still further in accordance with a preferred embodiment of the present invention, the at least one of the general purpose computer and the at least one controller computer serves as a backup for another one of the general purpose computer and the at least one controller computer.

There is also provided in accordance with yet another preferred embodiment of the present invention apparatus for collecting medical data including a user station connected to at least one computer remote from the user station via a computer network, a user interface connected to the user station, and a calibration system operative to calibrate the user interface which employs communication via the at least one computer network.

Further in accordance with a preferred embodiment of the present invention the said calibration system operates automatically without operator intervention.

Still further in accordance with a preferred embodiment of the present invention the apparatus for collecting medical data also includes personal parameter analysis software resident on at least one of the user station and the at least one computer for analyzing the at least one personal parameter of at least one user.

Preferably, analysis of at least one personal parameter of at least one user takes place partially at said user station and partially at the at least one computer.

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The analysis of at least one personal parameter of at least one user provides an analysis output which determines whether further analysis of the at least one personal parameter is carried out at the at least one computer.

Additionally in accordance with a preferred embodiment of the present invention, the at least one of the user stations and the at least one computer serves as a backup for another one of the user stations and the at least one computer.

There is also provided in accordance with yet another preferred embodiment of the present invention apparatus for collecting medical data including a general purpose computer, a user interface connected to said computer, a recording and storage facility for recording and storing at least one baseline result received by the user station using the user interface from at least a first test taken at least a first time, and a comparison facility for receiving at least one subsequent result received by the user station using the user interface from at least a second test, similar to the first test, taken at at least a second time, later than the first time, comparing the at least second test with the at least first test, applying a threshold to a comparison result and providing an indication in response to exceedance of the threshold.

There is further provided in accordance with another preferred embodiment of the present invention a user interface assembly suitable for use in apparatus for collecting medical data including a user station connected to at least one computer remote from said user station via a computer network, the user interface assembly includes a user interface coupled to said user station for use in collecting medical data from a subject, software usable by the user station to control the operation of the user interface and to communicate via the computer network with the at least one computer remote from the user station.

Further in accordance with a preferred embodiment of the present invention the software is useful at least to communicate data required for calibration of at least one of the user interface and the user station.

There is provided in accordance with yet another preferred embodiment of the present invention a user interface assembly suitable for use in apparatus for collecting medical data including a general purpose computer, the user interface assembly includes a user interface coupled to the user station for use in collecting medical data from a

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subject, software usable by the general purpose computer and providing at least the following functionality a recording and storage functionality for recording and storing at least one baseline result received by the general purpose computer via the user interface from at least a first test taken at at least a first time, and a comparison facility for receiving at least one subsequent result received by the general purpose computer using the user interface from at least a second test, similar to the first test, taken at at least a second time, later than the first time, comparing the at least second test with the at least first test, applying a threshold to a comparison result and providing an indication in response to exceedance of the threshold.

There is further provided in accordance with yet another preferred embodiment of the present invention a medical condition sensing system including a multiplicity of general purpose computers disposed in user locations and being connected via a computer network to at least one controller computer remote from at least one of the user locations, personal parameter measuring software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for measuring at least one personal parameter of at least one user, personal parameter analysis software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for analyzing the at least one personal parameter of at least one user.

Further in accordance with a preferred embodiment of the present invention the analysis of at least one personal parameter of at least one user takes place partially at a general purpose computer at at least one user location and partially at the at least one controller computer.

Still further in accordance with a preferred embodiment of the present invention the analysis of at least one personal parameter of at least one user at a general purpose computer at at least one user location provides an analysis output which determines whether further analysis of the at least one personal parameter is carried out at the at least one controller computer.

Additionally in accordance with a preferred embodiment of the present invention at least one of the general purpose computer and the at least one controller

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computer serves as a backup for another one of the general purpose computer and the at least one controller computer.

According to a second aspect of the present invention there is thus provided a parameter evaluation system comprising a boundary input device for setting boundaries in a variation range of one or more parameters, thereby to define regions within said variation range, a label input device for associating labels with said regions, a rule input device for setting rules to associate at least one of a plurality of output recommendations with each of said regions and with combinations thereof and an output device to present a user with an output recommendation associated with a region or combination thereof corresponding to at least one measured parameter input to said system.

In an embodiment, said boundary input device comprises a bar having a length representative of a variation range of a respective parameter.

In an embodiment, said boundary input device further comprises slidable boundary points for sliding along said length and wherein said regions are defined between said slidable boundary points.

In an embodiment, said label input device is operable to associate one of a plurality of labeling colors with at least one of said regions.

In an embodiment, said label input device is operable to associate a labeling color with a combination of said regions.

In an embodiment, said label input device is operable to label at least one of said regions with one of a group of categories.

In an embodiment, at least one of said categories is associated with a procedure for making automatic contact with a remote site.

In an embodiment, said procedure utilizes any one of a group comprising internet messaging, telephone messaging, paging and fax messaging to reach said remote site.

An embodiment further comprises an interface for connecting a measuring device thereto.

Preferably, there is further provided a measuring device attached to said interface for providing to said system a measured parameter.

In an embodiment, said parameter is a body medical parameter.

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Preferably, there is further provided a list of at least one symptom, selectable by a user and classifiable by said user according to degree of severity, and wherein said rule input device is usable to set rules which incorporate said rule input device with said parameters to produce said output.

In an embodiment, at least one parameter is signable to influence an output.

In accordance with a third aspect of the present invention there is further provided a parameter value region selection and categorization input device for setting boundaries in a variation range of a substantially continuously variable parameter, defining regions therebetween and categorizing said regions, said device comprising:

a visual representation of said variation range as a linear continuum,

a continuum divider for visually dividing said continuum at user selectable points therealong, said points corresponding to values of said parameter, thereby to define regions therebetween and

a category selector for associating one of a group of predefined categories with at least one thus-defined region.

In an embodiment, said continuum divider comprises a user-selectable number of sliders operable to be moved by a user to said user-selectable points.

In an embodiment, each one of said predefined categories has a color associated therewith and wherein said device is operable to display each-thus defined region on said continuum using said color.

Preferably, there is also provided an overlay unit for displaying said continuum in association with data connected with said parameter, thereby to assist in selection of said points.

Preferably, said overlay unit is a graphical overlay unit operable to display said continuum in association with data connected with said parameter and graphically arranged and scaled according to said continuum.

According to a fourth aspect of the present invention there is provided a parameter value region selection and categorization input device for setting boundaries in a variation range of a substantially continuously variable parameter, defining regions therebetween and categorizing said regions, said device comprising:

a visual representation of said variation range as a linear continuum,

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a continuum divider for visually dividing said continuum at user selectable points therealong, said points corresponding to values of said parameter, thereby to define regions therebetween and

a category definer for defining categories for association with said regions.

In an embodiment, said continuum divider comprises a user-selectable number of sliders operable to be moved by a user to said user-selectable points.

In an embodiment, said category definer comprises a facility for associating a color with a category that is defined and wherein said device is operable to display regions that have been associated with a given category on said continuum using said associated color.

Preferably, there is provided an overlay unit for displaying said continuum in association with data connected with said parameter, thereby to assist in selection of said points.

In an embodiment, said overlay unit is a graphical overlay unit operable to display said continuum in association with data connected with said parameter and graphically arranged and scaled according to said continuum.

According to a fifth aspect of the present invention, there is provided a method of associating a series of outputs with detected levels of a plurality of continuously varying parameters, said detected levels comprising an outcome, the method comprising

setting one or more boundary levels for each parameter, thereby defining regions between each boundary level,

associating categorization labels with each said defined region,

associating rules with each region and with combinations of regions of different parameters to associate a series of outputs with said regions and combinations, such that at least one of said series of outputs is produced by an outcome.

In an embodiment, at least one of said parameters is a body measurement and said output is a medical instruction.

According to a sixth aspect of the present invention there is provided a medical measurement categorization system comprising:

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a multiplicity of body measurement devices disposed in user locations and being connected via one or more networks to at least one controller computer remote from at least one of said user locations, said controller computer being equipped with a unified messaging facility to respond in a form suitable for different forms of network;

personal parameter measuring software resident on at least one data processing device for processing data output of at least one of said body measurement devices;

personal parameter categorization software resident on at least one of said data processing devices and said at least one controller computer for categorizing data output of at least one of said body measurement devices; and

output means for outputting an indication of said categorized data.

In an embodiment, said categorization software is operable to supply primary categorizations to individual measurements and a secondary categorization to combinations of said primary categorization.

Preferably, there is provided a memory for storing measurements and a comparator for comparing a current measurement with at least one corresponding stored measurement, wherein said categorization software is operative to apply a categorization to said current measurement based on the change between said current measurement and said at least one stored measurement.

Preferably, there is provided an input device for inputting boundary values of measurable parameters to define said categories.

Preferably, there is provided an input device for inputting boundary values of measurable parameters to define said primary categories and for inputting combination rules for combinations of said primary categories to define said secondary categories.

In an embodiment, a measurement is input to said system over a telephone via sound recognition apparatus able to interrogate a user and understand sound responses.

Preferably, there is provided a further output device, operable to output measurement data to show at least one of alarms, trends and data patterns.

Preferably, there is provided a unified messaging hierarchy for communicating using a hierarchy of messaging modes.

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According to a seventh aspect of the present invention there is provided a voicemail system for automatic communication with a user over a telephone network comprising an automatic telephone answering device comprising a sound processor and a data form, wherein said sound processor is operable to ask questions from said form in a voiced manner, to take in answers in sound format, to process said answers and to enter said answers onto said form.

In an embodiment, said form is a text form and wherein said sound processor is a text to sound processor.

In an embodiment, said sound format is telephone tone format.

In an embodiment, said sound format is voice and said sound processor comprises a voice recognition capability.

In an embodiment, said sound processor comprises voice to text capability.

Throughout this specification, reference to a physician includes any care provider or health care professional who is responsible for the patient.

Brief Description of the Drawings

For a better understanding of the invention and to show how the same may be carried into effect, reference will now be made, purely by way of example, to the accompanying drawings, in which:

Fig. 1 is a simplified partially pictorial, partially block diagram illustration of a medical condition sensing system constructed and operative in accordance with a preferred embodiment of the present invention.

Fig. 2 is a simplified functional block diagram illustration of the general functionality of a general purpose computer and of a personal parameter transmitting interface, both forming part of the system of Fig. 1;

Fig. 3 is a simplified functional block diagram illustration of the general functionality of a controller computer forming part of the system of Fig. 1;

Fig. 4 is a simplified flow chart illustration of the general functionality of the controller computer forming part of the system of Fig. 1;

Fig. 5A is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for lung sounds condition sensing;

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Fig. 5B is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for lung function condition sensing;

Fig. 5C is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for electrocardiogram sensing;

Fig. 5D is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for cardiac rhythm monitoring;

Fig. 5E is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for cardiac output condition sensing;

Fig. 5F is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for hearing condition sensing;

Fig. 5G is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for acute and chronic skin lesion monitoring sensing;

Fig. 5H is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for vision testing;

Fig. 6A is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5A;

Fig. 6B is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5B;

Fig. 6C is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5C;

Fig. 6D is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5D;

Fig. 6E is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5E;

Fig. 6F is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5F;

Fig. 6G is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5G;

Fig. 6H is a simplified functional block diagram of the system of Fig. 1 having the functionality shown in Fig. 5H;

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Fig. 7A is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5A and 6A;

Fig. 7B is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5B and 6B;

Fig. 7C is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5C and 6C;

Fig. 7D is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5D and 6D;

Fig. 7E is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5E and 6E;

Fig. 7F is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5F and 6F;

Fig. 7G is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5G and 6G;

Fig. 7H is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5H and 6H;

Fig. 8A is an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5A;

Fig. 8B is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5B;

Fig. 8C is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5C;

Fig. 8D is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5D;

Fig. 8E is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5E;

Fig. 8F is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5F;

Fig. 8G is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5G;

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Fig. 8H is a an illustration of application of part of an exemplary decision table to personal parameters of a given person in the operative environment of Fig. 5H;

Fig. 9a is a generalized diagram showing a home observation system according to a first embodiment of the present invention,

Fig. 9b is a generalized diagram showing a variation of the device of Fig. 9a,

Fig. 10 is a generalized block diagram of the system according to Fig. 9a,

Fig. 11 is a generalized diagram illustrating an operating principle of the present invention,

Fig. 12 is a generalized diagram showing a physician setting a home observation system of an embodiment of the present invention for a patient,

Fig. 13a is a generalized diagram showing a home observation system of a preferred embodiment of the present invention set to monitor systolic blood pressure,

Fig. 13b is a variation of the embodiment of Fig. 13b showing how the same system may be customized differently for a different patient,

Fig. 14a is a generalized diagram showing a home observation system of a preferred embodiment of the present invention set to monitor diastolic blood pressure,

Fig. 14b is a generalized diagram showing how the system of Fig. 14a may be customized differently for a different patient,

Fig. 15a is a generalized diagram showing a home observation system of a preferred embodiment of the present invention set to combine measurements of both systolic and diastolic blood pressure to produce an output that takes both measurements into account,

Fig. 15b is a generalized diagram showing the information of Fig. 15a in more concise format,

Figs. 16a to 16c are generalized diagrams showing a home observation system of a preferred embodiment of the present invention set to produce a different output from that of Fig. 15 from the same combined systolic and diastolic blood pressure measurements,

Figs. 17a to 17d are generalized diagrams showing a home observation system of a preferred embodiment of the present invention wherein different

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combinations of results of a series of measurements give rise to different output recommendations, and

Fig. 18 is a generalized block diagram showing a home observation system of a preferred embodiment of the present invention wherein a measuring device is connected to a data processing device arranged to process measurement data locally into output recommendations.

Fig. 19 is a generalized schematic diagram showing how a symptom may be incorporated into an embodiment of the present invention,

Fig. 20 is a generalized schematic diagram showing how symptoms and complaints may be customized into a home monitoring system on a per patient or per group of patients basis,

Fig. 21 is a generalized schematic diagram showing how five levels of symptom severity may be mapped onto the three system categorization levels,

Fig. 22 is a generalized schematic diagram contrasting the way in which a home monitoring system operative according to the present invention reports to a patient and reports to the physician or other care provider,

Fig. 23 is a generalized schematic diagram showing, in greater detail, how a home monitoring system of the present invention is operable to alert a physician to the status of a patient undergoing monitoring,

Fig. 24 is a generalized schematic diagram showing in greater detail how a home monitoring system of the present invention is operable to alert a patient to his status,

Fig. 25 is a generalized schematic diagram indicating customization levels for a home monitoring system operable in accordance with the present invention,

Fig. 26 is a generalized schematic diagram showing a data input form for allowing a physician to customize a home monitoring system on a per patient or per group of patients basis,

Fig. 27 is a generalized schematic diagram showing the data input form of Fig. 18 at a further stage in customization,

Figs. 28a to 28d are generalized schematic diagrams showing parameters and illustrating combinatorial rules for producing system outputs from the parameters,

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Figs. 29a to 29d are generalized schematic diagrams showing parameters and illustrating combinatorial rules for producing system outputs from the parameters,

Fig. 30 is a generalized schematic diagram showing the data input form of Fig. 26 at a further stage in customization, and

Fig. 31 is a generalized block diagram showing how a voice-mail system can be combined with data capture.

Description of the Preferred Embodiments

Reference is now made to Fig. 1, which is a simplified partially pictorial, partially block diagram illustration of a medical condition sensing system constructed and operative in accordance with a preferred embodiment of the present invention.

As seen in Fig. 1, the medical sensing system of the present invention comprises a multiplicity of general purpose computers 10, such as personal computers or communicators, disposed in user locations and connected via suitable wired or wireless connections 12 to a network 14, such as the Internet or other wide area network and via network 14 to at least one controller computer 16 remote from at least one of the user locations.

In accordance with a preferred embodiment of the invention, personal parameter measuring software 20 is resident on at least one of the general purpose computers 10 and/or on at least one controller computer 16 for measuring at least one personal parameter of at least one user of one of the general purpose computers. The personal parameters may be any suitable medical parameter, such as, for example, parameters relating to heart function, lung function, hearing, vision, alertness, physical appearance and perception as well as conventional medical indications such as weight, height, age, blood pressure, blood sugar level and other body fluid parameters, as well as various combinations of the foregoing.

Personal parameter measuring software 20 cooperates with personal parameter measuring equipment 22 which is preferably adapted to measure each type of personal parameter in association with a general purpose computer 10. Various types of personal parameter measuring equipment 22 may be provided to users of the system. For example, a stethoscope transducer 24 and lung sounds interface 26 may be provided for

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sensing lung sounds, electrocardiogram electrodes 27 and an electrocardiogram interface 28 may be provided for electrocardiogram measurements, and a hearing testing headset 32 and headset calibrator 34 may be provided for hearing testing.

It is appreciated that various calibration functionalities, which may be embodied in hardware, software or combinations thereof, may be provided as part of personal parameter measuring equipment 22 or for use therewith. The calibration functionalities may or may not involve communication with the controller computer 16 via the network 14. A given calibration functionality may operate automatically without operator intervention. Alternatively, a calibration functionality may require operator activity.

It is further appreciated that at every appropriate stage of operation, suitable instruction is provided to the user by the general purpose computer of the user. This instruction may be presented to the user in textual, audio or multi-media form and may be unidirectional or interactive. Preferably, suitable instruction is provided prior to calibration of personal parameter measuring equipment 22, prior to establishment of a baseline and prior to each test.

In accordance with a preferred embodiment of the present invention the medical condition sensing system of the present invention includes personal parameter reference generating software 33 resident on at least one of the general purpose computers or on at least one controller computer for establishing a reference for the at least one personal parameter. In this preferred embodiment, personal parameter comparison software, resident on at least one of the multiplicity of general purpose computers 10 and/or on at least one controller computer 16, compares at least one currently measured personal parameter with a corresponding reference and provides a comparison output.

The comparison output may be provided to the user by the general purpose computer 10 together with an action recommendation. Alternatively or additionally, it may be provided to a controller computer 16 for comparison with reference data stored on a central database 34 in order to provide additional information and recommendations to the user.

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A manned center 36 may be associated with the controller computer 16 for providing a human interface and/or input as required. The manned center 36, which is preferably staffed by physicians or other health professionals, may be in direct telephone and preferably videophone contact with the user. To this end video cameras 38 are preferably provided both at the manned center 36 and at various user locations. Communication of outputs of the video cameras 38 may be effected via network connections 12 or alternatively in any other manner.

In accordance with a preferred embodiment of the present invention, acceptable ranges of values for various medical parameters used in present invention may be established by medical personnel in the manned center 36 in accordance with the personal characteristics of each given patient.

In accordance with one embodiment of the present invention, initial feedback to the user may be provided under certain conditions by a general purpose computer 10 without accessing the network 14 or the controller computer 16.In accordance with a preferred embodiment of the present invention, communication via the network 14 with the controller computer 16 may be actuated automatically by the system, for example in response to a sensed personal parameter or to the comparison output being beyond a certain threshold. Communication via the network with the controller computer 16 may also be initiated by a user, at the user's initiative.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, for example in response to a sensed personal parameter or to the comparison output being beyond a given threshold. Communication with the manned center may also be initiated by a user, at the user's initiative. Communication between the user and the manned center may be via the network 14 and/or via conventional telephone or video-conference facilities.

Further in accordance with a preferred embodiment of the present invention, there is provided a recording and storage facility 40 for recording and storing sensed personal parameters.

Facility 40 may be provided both at general purpose computers 10 and at controller computer 16.

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There may also be provided for operation in the general purpose computer 10 or in the controller computer 16, software 42providing a comparison facility for comparing personal parameters and a threshold facility for applying a threshold to a comparison result and providing an indication in response to exceedance of the threshold. Software 42 may include signal processing functionality, where appropriate.

Additionally in accordance with a preferred embodiment of the present invention, there is provided software 44 which controls measurement of the personal parameters and which may communicate via the network 14 with at least one remote computer. Software 44, which may reside both at general purpose computers 10 and at controller computer 16, preferably provides encryption encoding of information communicated between general purpose computers 10 and controller computer 16.

Preferably there is associated with each general purpose computer 10, at least one of a display 50, a printer 52 and an audio input/output transducer 54, as well as a user graphics interface such as a mouse 56 and an IP telephone 58. A conventional telephone 59 is preferably available at each user location.

In accordance with a preferred embodiment of the present invention communication between a general purpose computer 10 via the network 14 with another general purpose computer 10 or with a controller computer 16 is encoded or encrypted using conventional technology suitable for this purpose.

Preferably, the controller computer 16 is provided with access to medical databases which provide reference material for presentation to user as well as information which can be used by the controller computer 16 to evaluate measured personal parameters and to determine suitable courses of treatment therefor.

In accordance with a preferred embodiment of the present invention, the medical condition sensing system of the present invention includes:

a multiplicity of general purpose computers disposed in user locations and being connected via a computer network to at least one controller computer remote from at least one of the user locations;

personal parameter measuring software resident on at least one of the multiplicity of general purpose computers and at least one controller computer for measuring at least one personal parameter of at least one user; and

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personal parameter analysis software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for analyzing at least one personal parameter of at least one user.

The distributed processing thus provided has a number of advantages, including reduced communication load and increased speed of response. Furthermore, such processing enables medical confidentiality to be readily maintained in communications over the computer network.

Preferably, at least one of the general purpose computer and the at least one controller computer serves as a backup for another one of the general purpose computer and the at least one controller computer.

This backup functionality preferably enables the system to overcome computer failures at either a general purpose computer at a user location or a controller computer, by transferring computing functionality to another computer connected thereto via the computer network. This is extremely important for emergency situations. Should a network failure occur, but the general purpose computer at the user location is functioning, the user nevertheless can receive basic information as well as indications and recommendations as described hereinbelow from the general purpose computer. Additionally a bypass telephone connection may be employed to provide necessary communication with a user.

Reference is now made to Fig. 2, which is a simplified functional block diagram illustration of the general functionality of a general purpose computer and of an optional personal parameter transmitting interface, both forming part of the system of Fig. 1. It is appreciated that the personal parameter transmitting interface typically forms part of personal parameter measuring equipment 22 (Fig. 1) and may have different configurations depending on the personal parameter which is sought to be measured and, in certain cases, may be obviated. Examples of personal parameter transmitting interfaces that do include hardware are interfaces 26 and 28 shown in Fig. 1. An example where the interface may be obviated is the hearing testing equipment employing the headset 32 shown in Fig. 1, which may be connected directly to the general purpose computer and may employ the sound card thereof.

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As seen in Fig. 2, personal parameter measurement equipment 100, such as stethoscope transducer 24 (Fig. 1), electrocardiogram electrodes 27 and headset 32, indicated generally at reference numeral 22 in Fig. 1, is coupled to optional personal parameter interface circuitry, designated generally by reference numeral 102. Circuitry 102 typically includes one or more of the following components: a filter 104, an amplifier 106, a memory 108, a microprocessor 110, a power supply 112, a wireless communications interface 114 and a wired communication interface 116. Where a memory 108 or a wireless interface 114 is provided, the interface circuitry 102 may be portable and thus particularly useful for emergency applications.

Typically the personal parameter interface circuitry 102 is coupled to a suitable port of a general purpose computer 10 (Fig. 1), such as a serial port, a sound or game port or a universal port and permits outputs to be supplied to the general purpose computer 10 for processing thereat.

Recording and storage facility 40 (Fig. 1) is provided preferably at general purpose computer 10 for recording and storing parameters received by the general purpose computer 10 during at least one test. Preferably, the recording and storage facility 40 comprises signal receipt and storage facility 120, a signal processing facility 122, a signal analysis facility 122 and an information storage facility 124. Optionally, any one or more of the foregoing functionalities may be obviated.

Software 42 (Fig. 1), which is preferably resident in general purpose computer 10, provides appropriate signal processing and comparison of parameters received by the general purpose computer 10 and may apply a threshold to a comparison result. Software 42 typically provides via the general purpose computer 10 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 42 typically comprises a comparison functionality 130 which may receive information representing a stored baseline and/or a test and which may provide an output to a threshold functionality 132. A condition description functionality 134 preferably receives information relating to at least one of the stored baseline and the test and may also receive outputs of the comparison and threshold functionalities 130 and 132. The condition description functionality preferably provides outputs to one or more

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of output devices 50, 52 and 54 (Fig. 1) as well as optionally via network 14 to controller computer 16 and/or to manned center 36.

The condition description functionality may also provide an output to recommendation functionality 136, which preferably also receives inputs from comparison functionality 130 and threshold functionality 132.

In accordance with a preferred embodiment of the present invention the general purpose computer 10 may communicate with a remote computer, such as a controller computer 16 (Fig. 1), for obtaining additional reference data and possibly carrying out a comparison between the test data and reference data, thereby to provide further information to the user. Such further information may include a more detailed or precise description of the condition indicated by the test results which may be accompanied by a more detailed or precise recommendation for action. Information received via the network may be employed by the recommendation functionality 136 as well as by the condition description functionality 134.

Communication with a remote computer, such as a controller computer 16 may be initiated automatically by the general purpose computer 10 via the network 14, for example in response to a sensed personal parameter or a comparison output beyond a certain threshold. Communication via the network 14 with the controller computer may also be initiated by a user, at the user's initiative.

Software 42 preferably also includes a standard personal parameter database 138 which stores normal values of personal parameters for a given user or users. The information stored in database 138 is preferably employed by one or more of functionalities 130, 132, 134 and 136.

Condition description functionality 134 and recommendation functionality 136 preferably operate in association with a database 140 which stores acceptable ranges of outputs of comparison functionality 130, normalized for age, weight, height, sex and possibly other characteristics. This database may be used for normalizing sensed personal parameters as well as for determining whether a baseline value indicates a need for evaluation or even urgent medical attention. Database 140 is preferably employed to enable condition description functionality 134 and recommendation functionality 136 to

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take into account the variation in acceptable changes in various personal parameters due to variations in age, weight, height, sex and possibly other characteristics.

It is appreciated that any one or more of the functionalities and databases described hereinabove in the context of software 42 may be obviated in a given application.

Communication with a remote computer, such as a controller computer 16 (Fig. 1) via the network 14 may be actuated automatically in response to the output of comparison functionality 130, threshold functionality 132, condition description functionality 134 or recommendation functionality 136. Thus, when a sensed personal parameter or the comparison output lies beyond a certain threshold which may indicate either an emergency situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 10 and the controller computer 16 via the network.

Communication between the user and the manned center may be via the network 14 and/or via conventional telephone or video-conference facilities.

Reference is now made to Fig. 3, which is a simplified functional block diagram illustration of the general functionality of a controller computer forming part of the system of Fig. 1. The controller computer, such as controller computer 16 (Fig. 1) preferably includes a communications facility 200 which enables it to communicate with a user's general purpose computer 10 (Fig. 1) via the network 14 (Fig. 1). This communication may include receiving information from a user as to which parameter measurement functionality the user is implementing and downloading to the user suitable operating, reference and calibration software to carry out that functionality.

The controller computer also preferably includes a user records database 202, which interfaces with the communications facility 200 and maintains all relevant records of user information, and a medical information database 204 which stores medical reference information useful in making comparisons and recommendations. The user records database 202 stores personal details of each user, general medical information regarding each user and results of tests conducted by the user, using the medical condition sensing kits, which are transmitted to the controller computer 16. Normally, the

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personal details, general medical information and results of the tests conducted on the patient, which are stored in the user records database 202, are also stored in the personal database 138 of the user's general purpose computer 10.

The controller computer also preferably includes decision functionality 206 which enables it to make decisions based on patient parameter, comparison and threshold information received from a user's general purpose computer 10 via network 14, using an analysis algorithm 208, such may be specific to each medical information sensing functionality provided by the system. The decisions made by functionality 206 may include decisions whether to automatically connect the user to a manned center 36 (Fig. 1) and whether to automatically summon emergency assistance for the user.

As indicated above, the controller computer also stores software to be downloaded to a user's general purpose computer 10 in a software storage facility 212. The controller computer also preferably includes a recording facility 210 for recording all communications with a user.

Reference is now made to Fig. 4, which is a simplified flow chart illustration of the general functionality of a controller computer forming part of the system of Fig. 1 and having the general structure described hereinabove with reference to Fig. 3.

Initial communication between a user's general purpose computer 10 (Fig. 1) and a controller computer, such as controller computer 16 (Fig. 1) preferably includes a user communicating with a web site of the controller computer 16, using communications functionality 200 (Fig. 3). In the course of this communications, the user may obtain demonstrations of various functionalities of system of the present invention and explanations regarding use of the system. The site may include transactional software enabling various medical condition sensing kits to be purchased by a user. Each such kit preferably includes all interfaces to be connected to the user's general purpose computer 10 and all necessary software to be installed by the user in the user's general purpose computer 10.

Alternatively or additionally the software may be downloaded by the user via the Internet or any other modality and the kit may be purchased or otherwise obtained not only from the web site but also from conventional retail sources.

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Irrespective of the manner in which the kit is obtained by the user and the software is installed in the user's general purpose computer, the user is required to register with the user records database 202 (Fig. 3). As noted above, the user records database stores personal details of each user, general medical information regarding each user and results of tests conducted by the user, using the medical condition sensing kits, which are transmitted to the controller computer.

When the user wishes to use the medical condition sensing kit in communication with the controller computer, following current use registration, in many cases an appropriate calibration protocol is followed, preferably using software installed at the controller computer. Following calibration, as and when appropriate, a baseline determination is carried out, as needed.

Once any and all calibration and baseline determination steps have been followed, a test may be conducted using the medical condition sensing kit in cooperation with the user's general purpose computer 10 which is in communication with the controller computer 16. In the course of the test or thereafter, the test results may be processed by decision functionality 206 in accordance with an analysis algorithm 208, which is typically kit specific. The processing typically employs stored in the user records database 202, such as calibration data and baseline data, and may also employ general (i.e. not patient specific) medical data stored in the medical information database 204.

Following processing of the test results as described hereinabove, decisions and recommendations are preferably provided to the user, preferably via the web site and the Internet. Additionally or alternatively, responsive to the test results and their relationship with established thresholds for the specific patient or for the type of test generally, an automatic connection may be established between the user and the manned center 36 (Fig. 1), via the web site of the controller computer and/or other media such as a telephone or video conference connection. Additionally, where appropriate, emergency assistance may be summoned to the user automatically or with human intervention. Preferably, all communications with the user and other parties as well as the entire decision making record are recorded for archival purposes.

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Reference is now made to Fig. 5A, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for lung sounds condition sensing. Fig. 5A shows two stages in lung sounds condition sensing, a first stage, indicated by designation I, at which a baseline reference is generated, and a second stage, indicated by designation II, at which an actual test is conducted. The context of Fig. 5A is typically a situation wherein a person, such as a child, has a possible respiration condition which is evidenced in lung sounds emitted during breathing.

In the environment of Fig. 5A, a user interface is provided which preferably includes a stethoscope transducer 310, such as transducer commercially available from Karmel Medical Acoustic Technologies Ltd. of Yokneam Illit, Israel. The stethoscope transducer 310 provides an electrical output typically via interface circuitry 312 to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 314.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 316, at general purpose computer 314 is operative for recording and storing at least one baseline plot of lung sounds received by the general purpose computer 314 from stethoscope transducer 310 during at least one first test taken at least a first time, such as on June 30, 1999. This first test is preferably carried out when the child is in apparent good health and shows no symptoms of respiratory distress and is employed to establish a baseline. The baseline result may be visualized by the waveform 317.

Software 42 (Fig. 1) here designated by reference numeral 318, which is preferably resident in general purpose computer 314, provides appropriate signal processing and comparison of lung sounds received by the general purpose computer 314 from stethoscope transducer 310 during a subsequent test taken at a a subsequent time, such as on August 15, 1999. This second test is preferably carried out when the person shows symptoms of respiratory distress and may require attention. It is seen that waveform 319 differs from baseline waveform 317.

Software 318 compares the lung sounds received during the second test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 318 typically provides via the general purpose computer

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314 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 318 typically compares various breathing parameters such as the slope of the waveform, the area under the waveform and the relationship between various portions of the waveform.

A controller computer 16 (Fig. 1), here designated by reference numeral 320, preferably communicates, via the network 14 (Fig. 1), with software 318 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the lung sounds may also be provided to the user. To enhance the efficacy of interface between the user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 322, may be located at the user location to enable personnel in the manned center 36 to view the patient who is experiencing apparent breathing distress.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 320, for example in response to lung sounds of a certain type or the output of a comparison of the currently sensed lung sounds with a baseline or with a standard reference which exceeds a threshold indicating a possibly critical condition or possibly improper use of the kit.

Reference is now made to Fig. 6A, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5A, namely lung sounds condition sensing, typically in an environment wherein a person, such as a child, has a possible respiration condition which is evidenced in the lung sounds emitted during breathing.

In the environment of Fig. 5A, as illustrated in Fig. 6A, stethoscope transducer 310 provides a lung sounds waveform via interface circuitry 312 (Fig. 5A) to recording and storage facility 316 (Fig. 5A) of general purpose computer 314 (Fig. 5A). As noted above with reference to Fig. 5A, preferably a baseline is initially established by a test conducted in an environment wherein a person, such as a child, is apparently breathing normally. Thereafter, a further test may be conducted when the person has a possible respiration condition which is evidenced in the lung sounds emitted during

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breathing. In both cases, the resulting waveform received from stethoscope transducer 310 is processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6A, interface circuitry 312 is preferably portable so as to be readily brought to the location of the patient and preferably employs a band pass filter 344 which filters out sounds picked up by the stethoscope transducer 310 outside a desired band, typically 80 - 4000 Hz, which includes both lung sounds and wheezing noises. The output of filter 344 is amplified by an amplifier 346 and preferably supplied to a memory 348. A portable power supply 352 preferably supplies power to the foregoing components as well as to a wireless communication interface 354 and/or a wired communication interface 356 which output to general purpose computer 314 (Fig. 5A).

In the embodiment of Fig. 6A, preferably, the recording and storage facility 316 stores both a baseline lung sounds waveform and an actual test lung sounds waveform. A lung sounds signal receipt and storage facility 360 receives and stores the signal received from interface 312. A signal processing facility 362 removes unwanted signal artifacts, such as wheezing signals having a duration less than 150 msecs, and generally prepares the signal for analysis.

A signal analysis functionality 364 preferably performs the following functions on the lung sounds signals:

Determination of the breathing rate;

Determination of the time relationship between durations of inhalation and exhalation;

Derivation of the slopes of the waveform at various stages during inhalation and exhalation;

Sensing the frequency pattern of the lung sounds;

Determination of the percentage of the duration of both inhalation and exhalation that wheezing occurs;

Sensing the presence of noises and other characteristic sound patterns in the lung sounds;

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Normalization of the above parameters for the age and height of the patient, using patient data from a personal database, typically forming part of software 318.

The outputs of the signal analysis functionality 364 for the signal is preferably stored in storage facility 366.

The above-described functionality provided by software 316 is applied initially to a baseline signal and thereafter to an actual test signal. The stored results for both the baseline signal and for the test signal are supplied to software 318.

Comparison functionality 130 (Fig. 2), here designated by reference numeral 370, which is included in software 318 (Fig. 5A), compares the lung sounds waveform and analysis data relating thereto stored by recording and storage facility 316 with a baseline lung sounds waveform and analysis data relating thereto, also stored by facility 316. Comparison functionality 370 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference numeral 372, which may apply a threshold to the comparison result indicating whether the currently sensed lung sounds substantially different from the baseline. Threshold functionality may employ data received from a personal database 374, which may also provide data to signal analysis functionality 364 of software 316 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 370 and thresholding functionality 372 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 375, which provides a description of the sensed respiratory condition via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1). Outputs provided by comparison functionality 370, thresholding functionality 372 and condition description functionality 375 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 376, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

Preferably, both condition description functionality 375 and recommendation functionality 376 receive reference data from a database 140 (Fig. 2), designated by reference numeral 380, which stores acceptable ranges of outputs of comparison functionality 370, normalized for age, weight, height, sex and possibly other

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characteristics. Database 380 is preferably employed to enable condition description functionality 375 and recommendation functionality 376 to take into account the variation in acceptable changes in various personal parameters due to variations in age, weight, height, sex and possibly other characteristics.

Communication with a remote computer, such as a controller computer 16 (Fig. 1) may be initiated automatically by the general purpose computer 314 via the network 14, for example in response to the output of comparison functionality 370, threshold functionality 372, condition description functionality 375 or recommendation functionality 376, indicating, for example a possibly acute respiratory condition or a suspected misuse of the kit.

Thus, when a sensed personal parameter or the comparison output lies beyond a certain threshold which may indicate either an emergency situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 314 and the controller computer 16 (Fig. 1) via the network 14 (Fig. 1). As noted above, communication via the network 14 with the controller computer 16 may also be initiated by a user, at the user's initiative.

Reference is now made to Fig. 7A, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5A and 6A.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a lung sound test kit including a stethoscope transducer and download of operating baseline establishment software to the user's general purpose computer 314 (Fig. 5A) from the controller computer 320 (Fig. 5A) or otherwise. The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database stores personal details of each patient for which the lung sounds sensing kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the lung sounds sensing kit, to the extent that such results are transmitted to the controller computer. Preferably, the information entered by the user into the user records database 202 of the controller computer 320. Thus, the personal details, general medical information and the results of

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the tests conducted on the patient, which are stored in the user records database 202, are also stored in the personal database 374 of the user's general purpose computer 314.

When the user is ready to perform a baseline establishing lung sounds test, following current use registration, a baseline determination is carried out typically in the following manner:

The lung sounds waveform is recorded at the user's general purpose computer 314.

The breathing rate is derived at the user's general purpose computer 314.

The time relationship between durations of inhalation and exhalation is derived at the user's general purpose computer 314.

The slopes of the waveform at various stages during inhalation and exhalation are derived at the user's general purpose computer 314.

The frequency pattern of the lung sounds is sensed at the user's general purpose computer 314.

The presence of noises and other characteristic sound patterns in the lung sounds is sensed at the user's general purpose computer 314. These noises and other characteristic sound patterns are preferably analyzed automatically to provide an output indication of frequency and amplitude.

Some of the above parameters are preferably normalized for the age and height of the patient.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8A, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

At a later time, when a test is carried out on the same patient who may be experiencing apparent respiratory distress, preferably all of the above listed parameters are measured and analyses are performed.Some of the above parameters are preferably normalized for the age and height of the patient.

At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose

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computer 314. Some or all of the parameters are preferably stored both at the user's general purpose computer 314 and in user records database 202 at the controller computer 320.

The general purpose computer 314 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 374 and 380, the operating software installed at the user's general purpose computer 314 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 314 may also employ inputs from the controller computer 320 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 320 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, the controller computer 320 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 320 may incur an additional charge, depending on the financial arrangements with the user.

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Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8A.

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The decision table of Fig. 8A is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 10 year child of height 140 cm.

As noted above, based on the application of the decision and indication/recommendations functionality, an indication/recommendations such as "INSIGNIFICANT CHANGE IN LUNG SOUNDS / NO ACTION REQUIRED", "POSSIBLY SIGNIFICANT CHANGE IN LUNG SOUNDS / CONTACT PHYSICIAN / REPEAT TEST", "SIGNIFICANT CHANGE IN LUNG SOUNDS / IMMEDIATELY INITIATE PHYSICIAN ORDERED TREATMENT / CONTACT PHYSICIAN IMMEDIATELY" and "HIGHLY SIGNIFICANT CHANGE IN LUNG SOUNDS / OBTAIN EMERGENCY TREATMENT IMMEDIATELY" may be made. In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 320 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources, such as breathing pattern analysis and lung noise analysis. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 120 and the manned center are maintained at the controller computer for future reference.

Turning to Fig. 8A, it is seen that for each of a plurality of relevant parameters, such as breathing rate, the ratio of durations of inhalation and exhalation, the percentage of the duration of inhalation at which wheezing noises are heard and the

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percentage of the duration of exhalation at which wheezing noises are heard, predicted, baseline and current test values are provided. Ratios and differences are calculated, as well as the ratio of the difference between the current test and the baseline to the baseline (D/B). Additionally or alternatively, the differences between a current test and previous tests and/or predicted values, as from databases 138 and 140 (Fig. 2), for the same patient may be determined and used.

The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 320 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8A, four categories, each having a different weighting, are defined. Category A includes parameters having a current to baseline difference or (D/B) ratio less than 15% and is given a weight of 0. Category B includes parameters having a current to baseline difference or (D/B) ration between 15% and 30% and is given a weight of 1. Category C includes parameters having a current to baseline difference or (D/B) ratio of between 30% and 40% and is given a weight of 2. Category D includes parameters having a current to baseline difference or (D/B) ratio exceeding 40% and is given a weight of 4.

It is appreciated that differences in different parameters may be measured in different ways, as most appropriate. For example in Fig. 8A, the differences in the breathing rate and the inhalation/exhalation duration ratio are measured as the ratio of current to baseline values. The differences in the wheezing percentage during both inhalation and exhalation are measured by subtracting the baseline value from the current value.

Thus it is seen in Fig. 8A that one parameter, namely wheezing percentage during inhalation, falls within Category A and one parameter, namely wheezing percentage during exhalation, falls within Category B. No parameters fall within

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Category C. Two parameters, breathing rate and inhalation/exhalation duration ratio fall within Category D. The resulting total weighted score is thus 9.

The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8A, is typically as follows:

Weighted Score Indication/Recommendation

0 - 2 "INSIGNIFICANT CHANGE IN LUNG SOUNDS / NO ACTION RE-

QUIRED" 3 - 4 "POSSIBLY SIGNIFICANT CHANGE IN LUNG SOUNDS / CONTACT

PHYSICIAN / REPEAT TEST"

5 - 8 "SIGNIFICANT CHANGE IN LUNG SOUNDS / IMMEDIATELY INITIATE

PHYSICIAN ORDERED TREATMENT / CONTACT PHYSICIAN IMMEDIAT-

ELY"

9 + "HIGHLY SIGNIFICANT CHANGE IN LUNG SOUNDS / OBTAIN EMERG-

ENCY TREATMENT IMMEDIATELY"

Accordingly, the recommendation in the example of Fig. 8A is "HIGHLY SIGNIFICANT CHANGE IN LUNG SOUNDS / OBTAIN EMERGENCY TREATMENT IMMEDIATELY".

It is a particular feature of the present invention that multiple levels of detail and analysis may be provided. The initial and lowest level of detail and analysis, such as that described hereinabove, may be provided by the user's general purpose computer. A higher level of detail and analysis may be provided by the controller computer which employs resources, including both information and analysis tools, which may not be available to the user's general purpose computer, and the manned center 36 (Fig. 1) which adds a real time human health professional input, which may be interactive with the user and/or the patient using both audio and video communication facilities.

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It is appreciated that when a particularly extreme difference is sensed in even one parameter, an emergency recommendation may be provided, irrespective of the status of the remaining parameters.

Preferably a full test and analysis report is prepared by the user's general purpose computer, which may incorporate inputs from the controller computer and the manned center as appropriate. This report may be printed out at the user location and may also be communicated via the network to any appropriate medical personnel or facility.

Reference is now made to Fig. 5B, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for lung function testing. Fig. 5B shows three stages in lung function testing, a first stage, indicated by designation I, at which calibration takes place; an optional second stage, indicated by designation II, at which a baseline reference is generated and a third stage, indicated by designation III, at which an actual test is conducted. The context of Fig. 5B is typically a situation wherein a person has a possible respiration condition which is evidenced in shortness of breath.

In the environment of Fig. 5B, a user interface is provided which preferably includes a flowmeter transducer 410, such as a Spirolyser SPL-10 flowmeter commercially available from F.I.M. SA of Lyon, France. The flowmeter transducer 410 typically provides an electrical output typically via interface circuitry 412, typically incorporated therein, to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 414. Preferably, interface circuitry 412 is incorporated within a housing which also encloses flowmeter transducer 410.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 416, at general purpose computer 414 is operative for recording and storing calibration data and at least one baseline plot of lung function, typically a plot of forced expirium, received by the general purpose computer 414 from flowmeter transducer 410.

Prior to generating a baseline plot of lung function, the flowmeter transducer 410 is calibrated, as indicated at I in Fig. 5B. A syringe 417 containing a known amount of air, typically one liter, is employed to supply the known quantity to the flowmeter transducer 410. The software contained in the user's general purpose computer

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automatically calibrates the sensed output of the flowmeter transducer 410 to the fixed volume.

Following calibration of the flowmeter transducer 410, the baseline plot is generated by carrying out a baseline test, as seen at II in Fig. 5B. This baseline test is preferably carried out when the person is in apparent good health and shows no symptoms of respiratory distress.

Software 42 (Fig. 1), here designated by reference numeral 419, which is preferably resident in general purpose computer 414, provides appropriate signal processing and comparison of lung function indications received by the general purpose computer 414 from flowmeter transducer 410. Software 419 preferably provides an indication of average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled.

Following establishment of the baseline reference, an actual test is carried out at a subsequent time, as indicated at III in Fig. 5B. The actual test is preferably carried out when the person shows symptoms of respiratory distress and may require attention. It is seen that the test results for the actual test, shown at III, differ from the test results for the baseline reference, shown at II.

Software 419 compares the lung function received during the actual test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 419 typically provides via the general purpose computer 414 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 419 typically compares various breathing parameters such as the forced expirium waveform 418, the Forced Vital Capacity (FVC), the Forced Expiratory Volume during the first second of the forced expirium and the peak flow rate (PF) and the average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled (FEF 25% - 75%).

As described hereinabove, a controller computer 16 (Fig. 1), here designated by reference numeral 420, preferably communicates with software 419 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the lung function may also be provided to the

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user. To enhance the efficacy of interface between a user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 422, may be located at the user location to enable personnel in the manned center 36 to view the patient who is experiencing apparent breathing distress.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 420, for example in response to lung function of a certain type or the output of a comparison of the currently sensed lung function with a baseline or with a standard reference which exceeds a threshold indicating a possibly critical condition or possibly improper use of the kit.

Reference is now made to Fig. 6B, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5B, namely lung function testing, typically in an environment wherein a person has a possible respiration condition which is evidenced in the lung function indications sensed during breathing.

In the environment of Fig. 5B, as illustrated in Fig. 6B, flowmeter transducer 410 provides a lung function waveform via interface circuitry 412 (Fig. 5B) to recording and storage facility 416 (Fig. 5B) of general purpose computer 414 (Fig. 5B). As noted above with reference to Fig. 5B, preferably a baseline is initially established by a test conducted in an environment wherein a person is apparently breathing normally. Thereafter, a further test may be conducted when the person has a possible respiration condition which is evidenced in the lung function parameters sensed during breathing. In both cases, the resulting waveform received from flowmeter transducer 410 is processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6B, interface circuitry 412 preferably employs an amplifier 446 which outputs via a wired communication interface 464 which is coupled to general purpose computer 414 (Fig. 5B). A microprocessor 450 may be provided to govern the operation of the flowmeter transducer 410 and to perform other functions.

In the embodiment of Fig. 6B, preferably the recording and storage facility 416 stores both baseline lung function data and actual test lung function data. A lung function waveform receipt and storage facility 460 receives and stores data received

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from interface 412. A signal processing facility 462 removes unwanted data artifacts and generally prepares the data for analysis.

A signal analysis functionality 464 preferably performs the following functions on the lung function data:

For both the baseline and the actual test data , determination of various breathing parameters such as the forced expirium waveform 418 (Fig. 5B), the Forced Vital Capacity (FVC), the Forced Expiratory Volume during the first second of the forced expirium (FEV1) as well as the peak flow rate (PF) and the average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled (FEF 25% - 75%).

The outputs of the signal analysis functionality 464 are preferably stored in storage facility 466.

The above-described functionality provided by software 416 is applied initially to a baseline signal and thereafter to an actual test signal. The stored results for both the baseline signal and for the test signal are supplied to software 419.

Software 419 preferably comprises comparison functionality 130 (Fig. 2), here designated by reference numeral 470, which compares the lung function analysis data relating to an actual test, stored by recording and storage facility 466 with baseline lung function analysis data also stored by facility 466 and preferably also with expected values for such lung functional analysis data which may be received from personal database 140 (Fig. 2) here designated by reference numeral 471.

The comparison functionality 470 preferably provides comparison of measured, predicted and baseline values of various breathing parameters such as the forced expirium waveform 418 (Fig. 5B), the Forced Vital Capacity (FVC), the Forced Expiratory Volume during the first second of the forced expirium (FEV1) as well as the peak flow rate (PF) and the average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled (FEF 25% - 75%).

The comparison functionality 470 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference

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numeral 472, which may apply a threshold to the comparison result indicating whether the currently sensed lung function substantially different from the baseline and/or from the expected values therefor. Threshold functionality 472 may employ data received from a personal database 471, which may also provide data to signal analysis functionality 464 of software 416 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 470 and thresholding functionality 472 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 474, which provides a description of the sensed respiratory condition via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1). Outputs provided by comparison functionality 470, thresholding functionality 472 and condition description functionality 474 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 476, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54

Preferably, both condition description functionality 474 and recommendation functionality 476 also receive reference data from database 471.

Preferably, both condition description functionality 474 and recommendation functionality 476 receive reference data from a database 140 (Fig. 2), here designated by reference numeral 480, which stores acceptable ranges of outputs of comparison functionality 470, normalized for age, weight, height, sex and possibly other characteristics. Database 480 is preferably employed to enable condition description functionality 474 and recommendation functionality 476 to take into account the variation in acceptable changes in various personal parameters due to variations in age, weight, height, sex and possibly other characteristics.

Communication with a remote computer, such as a controller computer 16 (Fig. 1) may be initiated automatically by the general purpose computer 414 via the network 14, for example in response to the output of comparison functionality 470, threshold functionality 472, condition description functionality 474 or recommendation functionality 476, indicating, for example a possibly acute respiratory condition or a suspected misuse or malfunction of the kit.

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Thus, when one or more sensed lung function parameters or the comparison output lies beyond a certain threshold which may indicate either an emergency situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 414 and the controller computer 16 (Fig. 1) via the network 14 (Fig. 1). Communication via the network 14 with the controller computer 16 may also be initiated by a user, at the user's initiative.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. It is thus possible for medical personnel in the manned center 36 to directly view the patient while hearing the lung function directly and speaking with the user.

Reference is now made to Fig. 7B, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5A and 6A.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a lung function test kit including flowmeter transducer 410, interface 412 and calibration syringe 417 (Fig. 5B) and download of operating baseline establishment software to the user's general purpose computer 414 (Fig. 5B) from the controller computer 420 (Fig. 5B) or otherwise.

The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database stores personal details of each patient for which the lung function sensing kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the lung function sensing kit, to the extent that such results are transmitted to the controller computer. Preferably, the information entered by the user into the user records database of the controller computer 420 and the results of the tests conducted on the patient, which are stored in the user records database 202, are also stored in the personal database 471 of the user's general purpose computer 414.

Calibration of the flowmeter 410 is preferably carried out by using syringe 417 to cause a measured amount of air, typically 1 liter, to pass through the flowmeter 410. The output of the flowmeter 410 is adjusted, as necessary, to provide an output indicating the measured amount of air.

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When the user is ready to perform a baseline establishing lung function test, following current use registration and calibration of the flowmeter 410, a baseline test is carried out as seen at II in Fig. 5B. This baseline test is preferably carried out when the person is in apparent good health and shows no symptoms of respiratory distress.

Software 419 provides appropriate signal processing and comparison of lung function parameters received by the general purpose computer 414 from flowmeter transducer 410. Software 419 preferably provides an indication of average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8B, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

Following establishment of the baseline reference, an actual test is carried out at a subsequent time, as indicated at III in Fig. 5B. The actual test is preferably carried out when the person shows symptoms of respiratory distress and may require attention. Some or all of the parameters are preferably stored both at the user's general purpose computer 414 and in user records database 202 at the controller computer 420. Some of the above parameters are preferably normalized for the age and height of the patient.

Software 419 compares the lung function received during the actual test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 419 typically provides via the general purpose computer 414 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 419 typically compares various breathing parameters such as the forced expirium waveform 418, the Forced Vital Capacity (FVC), the Forced Expiratory Volume during the first second of the forced expirium and the peak flow rate (PF) and the average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled (FEF 25% - 75%).

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At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 414.

At a later time, when a test is carried out on the same patient who may be experiencing apparent respiratory distress, preferably all of the above listed parameters are measured and analyses are performed.

The general purpose computer 414 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 471 and 480, the operating software installed at the user's general purpose computer 414 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 414 may also employ inputs from the controller computer 420 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 420 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, the controller computer 420 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 420 may incur an additional charge, depending on the financial arrangements with the user.

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Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8B.

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The decision table of Fig. 8B is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 37 year male of height 172 cm and weight 67 kg.

Based on the application of the decision and indication/recommendation functionality, an indication/recommendation such as "INSIGNIFICANT CHANGE IN LUNG FUNCTIONS / NO ACTION REQUIRED", "POSSIBLY SIGNIFICANT CHANGE IN LUNG FUNCTIONS / CONTACT PHYSICIAN / REPEAT TEST", "SIGNIFICANT CHANGE IN LUNG FUNCTIONS / IMMEDIATELY INITIATE PHYSICIAN ORDERED TREATMENT / CONTACT PHYSICIAN IMMEDIATELY" and "HIGHLY SIGNIFICANT CHANGE IN LUNG FUNCTIONS / OBTAIN EMERGENCY TREATMENT IMMEDIATELY" may be made. In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 420 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources, such as breathing pattern analysis and lung noise analysis. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 420 and the manned center are maintained at the controller computer 420 for future reference.

Turning to Fig. 8B, it is seen that for each of a plurality of relevant parameters, such as the forced expirium waveform 418, the Forced Vital Capacity (FVC), the Forced Expiratory Volume during the first second of the forced expirium (FEV1) and the peak flow rate (PF) and the average expiration flow rate during that

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portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled (FEF 25% - 75%), predicted, baseline and current test values are provided. Ratios may be calculated. Additionally or alternatively, the differences between a current test and previous tests and/or predicted values, as from databases 138 and 140 (Fig. 2), for the same patient may be determined and used.

The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 420 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8B, four categories, each having a different weighting, are defined. Category A includes parameters having a current to baseline (C/B) difference less than 20% and is given a weight of 0. Category B includes parameters having a current to baseline (C/B) difference between 20% and 35% and is given a weight of 2. Category C includes parameters having a C/B difference of between 35% and 50% and is given a weight of 4. Category D includes parameters having a C/B difference exceeding 50% and is given a weight of 9.

It is appreciated that differences in different parameters may be measured in different ways, as most appropriate. In the example of Fig. 8B, however, the differences in the forced expirium waveform 418, the Forced Vital Capacity (FVC), the Forced Expiratory Volume (FEV1) during the first second of the forced expirium and the peak flow rate (PF) and the average expiration flow rate during that portion of the expirium at which between 25% and 75% of the air in the lungs has been expelled (FEF 25% - 75%) are all measured as the ratio of current to baseline values.

Thus it is seen in Fig. 8B that no parameter falls within Category A and two parameters, namely FVC and FEV1, fall within Category B. Two parameters, FEF 25% - 75% and PF fall within Category C. No parameters fall within Category D. The resulting total weighted score is thus 12.

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The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8B, is typically as follows:

Weighted Score Indication/Recommendation

0 - 2 "INSIGNIFICANT CHANGE IN LUNG FUNCTIONS / NO ACTION RE-

QUIRED"

3 - 4 "POSSIBLY SIGNIFICANT CHANGE IN LUNG FUNCTIONS / CONTACT

PHYSICIAN / REPEAT TEST" 5 - 8 "SIGNIFICANT CHANGE IN

LUNG FUNCTIONS / IMMEDIATELY INITIATE PHYSICIAN

ORDERED TREATMENT / CONTACT PHYSICIAN IMMEDIATELY"

9 + "HIGHLY SIGNIFICANT CHANGE IN LUNG FUNCTIONS / OBTAIN

EMERGENCY TREATMENT IMMEDIATELY"

Accordingly, the recommendation in the example of Fig. 8B is "HIGHLY SIGNIFICANT CHANGE IN LUNG FUNCTIONS / OBTAIN EMERGENCY TREATMENT IMMEDIATELY".

Reference is now made to Fig. 5C, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for electrocardiogram testing. Fig. 5C shows three stages in electrocardiogram testing, a first stage, indicated by designation I, at which calibration takes place; a second stage, indicated by designation II, at which a baseline reference is generated and a third stage, indicated by designation III, at which an actual test is conducted. The context of Fig. 5C is typically a situation wherein a person has an interest in determining possible changes in his electrocardiogram, such as following aerobic exercise or when experiencing shortness of breath or chest pains.

In the environment of Fig. 5C, a user interface is provided which preferably includes a 12 lead ECG recorder/transmitter 510, such as a HEARTVIEW R ECG recorder/transmitter commercially available from Aerotel Ltd. of Holon, Israel. The 12 lead ECG recorder/transmitter 510 typically provides an electrical output directly or via

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a suitable audio coupler to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 514.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 516, at general purpose computer 514 is operative for recording and storing calibration data and at least one baseline electrocardiogram received by the general purpose computer 514 from 12 lead ECG recorder/transmitter 510.

Prior to generating a baseline electrocardiogram, the 12 lead ECG recorder/transmitter 510 is calibrated, as indicated at I in Fig. 5C. Typically a 1mV signal generator 518 is employed to apply a 1mV signal to the interface of the general purpose computer to which the recorder/transmitter 510 is connected. The general purpose computer is typically calibrated such that the amplitude of the 1mV signal appears as 10 mm in the Y direction. The software contained in the user's general purpose computer automatically carries out this calibration.

Following calibration of the 12 lead ECG recorder/transmitter 510, a baseline electrocardiogram is generated by carrying out a baseline test, as seen at II in Fig. 5C. This baseline test is preferably carried out when the person is in apparent good health and shows no symptoms of stress or distress.

Software 42 (Fig. 1), here designated by reference numeral 519, which is preferably resident in general purpose computer 514, provides appropriate signal processing and comparison of electrocardiogram indications received by the general purpose computer 514 from 12 lead ECG recorder/transmitter 510.

Following establishment of the baseline reference, an actual test is carried out at a subsequent time, as indicated at III in Fig. 5C. The actual test is preferably carried out when the person shows symptoms of stress or distress and may require attention. It is seen that the test results for the actual test, shown at III, differ from the test results for the baseline reference, shown at II.

Software 519 compares the electrocardiogram received during the actual test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 519 typically provides via the general purpose computer 514 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

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Software 519 typically compares various measured ECG parameters for each lead, such as the heart rate, R-R interval, P-R interval, Q-S interval, Q-T interval, and the height of the S - T segment as compared with the height of the P - Q segment and the T - P segment. Software 519 may also compare various calculated ECG parameters, such as the following parameters: Q/R ratio for each lead and the overall axes for all leads of the QRS, P and T waves.

A controller computer 16 (Fig. 1), here designated by reference numeral 520, preferably communicates with software 519 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the electrocardiogram may also be provided to the user. To enhance the efficacy of interface between the user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 522, may be located at the user location to enable personnel in the manned center 36 to view the patient whose electrocardiogram is being taken.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 520, for example in response to electrocardiogram of a given configuration or the output of a comparison of the currently sensed electrocardiogram with a baseline or with a standard reference which exceeds a threshold indicating a possibly critical condition or possibly improper use of the kit.

Reference is now made to Fig. 6C, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5C, namely electrocardiogram testing, typically in an environment wherein a person has an interest in determining possible changes in his electrocardiogram, such as following aerobic exercise or when experiencing shortness of breath or chest pains.

In the environment of Fig. 5C, as illustrated in Fig. 6C, 12 lead ECG recorder/transmitter 510 provides a electrocardiogram output to recording and storage facility 516 (Fig. 5C) of general purpose computer 514 (Fig. 5C). As noted above with reference to Fig. 5C, preferably a baseline is initially established by a test conducted in an environment wherein a person is relaxed. Thereafter, a further test may be conducted when the person experiences stress or distress. In both cases, the resulting signals

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received from 12 lead ECG recorder/transmitter 510 are processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6C, preferably the recording and storage facility 516 stores both baseline electrocardiogram data and actual test electrocardiogram data. A electrocardiogram receipt and storage facility 560 receives and stores data received from recorder/transmitter 510. A signal processing facility 562 removes unwanted data artifacts and generally prepares the data for analysis.

A signal analysis functionality 564 preferably performs the following functions on the electrocardiogram data:

Measurement of ECG parameters for each lead, such as the heart rate, Q/R ratio, R-R interval, P-R interval, Q-S interval, Q-T interval, and the height of the S - T segment as compared with the height of the P - Q segment and the T - P segment;

Calculation of various ECG parameters, such as the following parameters: Q/R ratio for each lead and the overall axes for all leads of the QRS, P and T waves.

The outputs of the signal analysis functionality 564 are preferably stored in storage facility 566.

The above-described functionality provided by software 516 is applied initially to a baseline electrocardiogram and thereafter to an actual test electrocardiogram. The stored results for both the baseline signal and for the test signal are supplied to software 519.

Software 519 preferably comprises comparison functionality 130 (Fig. 2), here designated by reference numeral 570, which compares the electrocardiogram analysis data relating to an actual test, stored by recording and storage facility 560 with baseline electrocardiogram analysis data also stored by facility 560 and preferably also with expected values for such electrocardiogram analysis data which may be received from database 140 (Fig. 2) here designated by reference numeral 571.

The comparison functionality 570 preferably provides comparison of measured, predicted and baseline values of various electrocardiogram parameters such as measured ECG parameters for each lead, such as the heart rate, R-R interval, P-R interval, Q-S interval, Q-T interval, and the height of the S - T segment as compared with the height of the P - Q segment and the T - P segment as well as various calculated

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ECG parameters, such as the following parameters: Q/R ratio for each lead and the overall axes for all leads of the QRS, P and T waves. The predicted values fall within known normal limits for each parameter.

The comparison functionality 570 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference numeral 572, which may apply a threshold to the comparison result indicating whether the currently sensed electrocardiogram parameters are substantially different from the baseline and/or from the expected values therefor. Threshold functionality may employ data received from a personal database 573, which may also provide data to signal analysis functionality 564 of software 516 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 570 and thresholding functionality 572 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 574, which provides a description of the sensed electrocardiogram indications via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1).

Outputs provided by comparison functionality 570, thresholding functionality 572 and condition description functionality 574 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 576, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

Preferably, both condition description functionality 574 and recommendation functionality 576 also receive reference data from database 571.

Preferably, both condition description functionality 574 and recommendation functionality 576 receive reference data from a database 140, here designated by reference numeral 580, which stores acceptable ranges of outputs of comparison functionality 570, normalized for age and possibly other characteristics. Database 580 is preferably employed to enable condition description functionality 574 and recommendation functionality 576 to take into account the variation in acceptable changes in various personal parameters due to variations in age and possibly other characteristics.

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Communication with a remote computer, such as a controller computer 16 (Fig. 1) may be initiated automatically by the general purpose computer 514 via the network 14, for example in response to the output of comparison functionality 570, threshold functionality 572, condition description functionality 574 or recommendation functionality 576, indicating, for example a possibly acute cardiac condition or a suspected misuse or malfunction of the kit.

Thus, when one or more sensed electrocardiogram parameters or the comparison output lies beyond a certain threshold which may indicate either an emergency situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 514 and the controller computer 16 (Fig. 1) via the network 14 (Fig. 1). Communication via the network 14 with the controller computer 16 may also be initiated by a user, at the user's initiative.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. It is thus possible for medical personnel in the manned center 36 to directly view the patient while viewing the electrocardiogram directly and speaking with the user.

Reference is now made to Fig. 7C, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5C and 6C.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a electrocardiogram test kit including 12 lead ECG recorder/transmitter 510 and 1mV generator 518 for calibration (Fig. 5C) and download of operating baseline establishment software to the user's general purpose computer 514 (Fig. 5C) from the controller computer 520 (Fig. 5C) or otherwise.

The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database 202 stores personal details of each patient for which the electrocardiogram kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the electrocardiogram sensing kit, to the extent that such results are

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transmitted to the controller computer. Preferably, the information entered by the user into the user records database 202 of the controller computer 520 such as personal details and general medical information as well as results of the tests conducted on the patient, which are also stored in the personal database 573 of the user's general purpose computer 514.

Calibration of the recorder/transmitter 410 is preferably carried out by using 1 mV generator 518.

When the user is ready to perform a baseline electrocardiogram test, following current use registration and calibration of the recorder/transmitter 510, a baseline test is carried out as seen at II in Fig. 5C. This baseline test is preferably carried out when the person is relaxed and in apparent good health.

Software 519 provides appropriate signal processing and comparison of electrocardiogram indications received by the general purpose computer 514 from 12 lead ECG recorder/transmitter 510. Software 519 preferably provides the following parameters:

Measured ECG parameters for each lead, such as the heart rate, R-R interval, P-R interval, Q-S interval, Q-T interval, and the height of the S - T segment as compared with the height of the P - Q segment and the T - P segment;

Calculated ECG parameters, such as the following parameters: Q/R ratio for each lead and the overall axes for all leads of the QRS, P and T waves.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8C, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 514. Some or all of the parameters are preferably stored both at the user's general purpose computer 514 and in user records database 202 at the controller computer 520.

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At a later time, when a test is carried out on the same patient who may be experiencing stress or distress, preferably all of the above listed parameters are measured and analyses are considered. Some of the above parameters are preferably normalized for the age of the patient.

The general purpose computer 514 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 574 and 580, the operating software installed at the user's general purpose computer 514 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 514 may also employ inputs from the controller computer 520 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 520 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, the controller computer 520 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 520 may incur an additional charge, depending on the financial arrangements with the user.

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Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8C.

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The decision table of Fig. 8C is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 40 year male.

As noted above, based on the application of the decision and indication/recommendation functionality, an indication/recommendation such as "INSIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / NO ACTION REQUIRED", "POSSIBLY SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / CONTACT PHYSICIAN / REPEAT TEST", and "SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / OBTAIN EMERGENCY TREATMENT IMMEDIATELY" may be made. In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 420 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources, such as pattern analysis, measuring P - P intervals and comparison thereof to R - R intervals. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician, may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 520 and the manned center are maintained at the controller computer 520 for future reference.

Turning to Fig. 8C, it is seen that for each of a plurality of relevant parameters, such as heart rate, Q/R ratio, P - R interval, Q - S interval, QRS axis, T axis, S - T segment height, normal limits as well as baseline and current test values are provided. Ratios may be calculated. Additionally or alternatively, the differences

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between a current test and previous tests and/or normal limits, as from databases 573 and 580, for the same patient may be determined and used.

In this case independent weighting is preferably given both to the difference between current test values and baseline values and to the relationship between current test values and normal limits for such values. The differences and the relationships are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 520 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8C, four categories, each having a different weighting, are defined. Category A includes parameters having a ratio of current to baseline difference to baseline (D/B) than 20% and is given a weight of 0. Category B includes parameters having a ratio of current to baseline difference to baseline (D/B) between 20% and 30% and is given a weight of 2. Category C includes parameters having a ratio of current to baseline difference to baseline (D/B) greater than 30% and is given a weight of 4. Category D includes parameters which exceed normal limits, preferably according to physician's decision, and is giving a weight of 6.

It is appreciated that differences in different parameters may be measured in different ways, as most appropriate. In the example of Fig. 8C, however, differences in the heart rate, the P - R interval, the Q - S interval, the QRS Axis, The T Axis and the S - T segment height are all measured as the ratio of current to baseline values.

Thus it is seen in Fig. 8C that the Q - S interval falls within Category A and the heart rate and QRS Axis fall within Category B. Two parameters, the P - R interval and the T Axis fall within Category C. Three parameters, the heart rate, the Q - S interval, and the S-T segment height are outside their normal limits and thus fall within Category D. The resulting total weighted score is thus 30.

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The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8C, is typically as follows:Weighted Score Indication/Recommendation

0 - 2 "INSIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / NO ACTION

REQUIRED"

3 - 8 "POSSIBLY SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM /

CONTACT PHYSICIAN / REPEAT TEST"

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9 + "SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / OBTAIN EMERGENCY
TREATMENT IMMEDIATELY"

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Accordingly, the recommendation in the example of Fig. 8C is "SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / OBTAIN EMERGENCY TREATMENT IMMEDIATELY".

In this example, if the total exceeds typically 16, the manned center 36 is immediately invoked.

Reference is now made to Fig. 5D, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for prolonged electrocardiogram testing, otherwise known as Holter monitoring. Fig. 5D shows a single stage in prolonged electrocardiogram testing. The context of Fig. 5D is typically a situation wherein a person wishes to monitor his heart rate and to determine whether and to what extent there exists disrhythmia.

In the environment of Fig. 5D, a user interface 612 is provided which preferably includes a 3 - 4 lead ECG recorder/transmitter 610, such as a HEARTVIEW R ECG recorder/transmitter commercially available from Aerotel Ltd. of Holon, Israel. The ECG recorder/transmitter 610 typically provides an electrical output directly or via a suitable audio coupler or other interface 612 to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 614.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 616, at general purpose computer 614 is operative for recording and storing data received by the general purpose computer 614 from ECG recorder/transmitter 610. An actual test is preferably carried out whenever appropriate.

Software 619, preferably resident in general purpose computer 614, compares electrocardiogram derived data received during the actual test with electrocardiogram derived data produced during at least one earlier test and may apply a threshold to the comparison result. Software 619 typically provides via the general purpose computer 614 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 619 also includes a Holter monitoring software (24 hrs. ECG recording and monitoring) which is commercially available from many sources, such as Schiller AG, CH-6340 Baar, Switzerland.

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Software 619 also typically compares various measured ECG parameters for each lead, such as the heart rate, R-R interval, P-P interval, P-R interval and Q-S interval. Software 619 may also compare various calculated ECG parameters related to disrhythmia including frequency of premature beats (PMB).

A controller computer 16 (Fig. 1), here designated by reference numeral 620, preferably communicates with software 619 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the electrocardiogram may also be provided to the user. To enhance the efficacy of interface between a user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 622, may be located at the user location to enable personnel in the manned center 36 to view the patient whose electrocardiogram is being taken.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 620, for example in response to electrocardiogram derived data or the output of a comparison of the currently sensed electrocardiogram derived data with corresponding data from a previous electrocardiogram or with a standard reference which exceeds a threshold indicating a possibly critical condition or possibly improper use of the kit.

Reference is now made to Fig. 6D, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5D, namely prolonged electrocardiogram testing, typically in an environment wherein a person wishes to monitor his heart rate and to determine whether and to what extent there exists disrhythmia.

In the environment of Fig. 5D, as illustrated in Fig. 6D, ECG recorder/transmitter 610 provides a electrocardiogram output via interface 612 to recording and storage facility 616 (Fig. 5D) of general purpose computer 614 (Fig. 5D). As noted above with reference to Fig. 5D, preferably multiple tests are conducted at different times. The resulting signals received from ECG recorder/transmitter 610 are processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

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In the embodiment of Fig. 6D, interface circuitry 612 is preferably portable so as to be carried by the patient and preferably employs a band pass filter 644 which filters out spurious and extraneous noise outside a desired band, centered on about 1900 Hz. The output of filter 644 is amplified by an amplifier 646 and preferably supplied to a memory 648. A portable power supply 652 preferably supplies power to the foregoing components as well as to a wireless communication interface 654 and/or a wired communication interface 656 which output to general purpose computer 614 (Fig. 5D).

In the embodiment of Fig. 6D, preferably the recording and storage facility 616 stores both previously derived electrocardiogram data and current test electrocardiogram data. A electrocardiogram receipt and storage facility 660 receives and stores data received from recorder/transmitter 610. A signal processing facility 662 removes unwanted data artifacts and generally prepares the data for analysis.

A signal analysis functionality 664 preferably performs the following functions on the electrocardiogram data:

Measurement of ECG parameters for each lead, such as the heart rate, Q/R ratio, R-R interval, P-P interval, P-R interval and Q-S interval.

Calculation of various ECG parameters relevant to disrhythmia.

The outputs of the signal analysis functionality 664 are preferably stored in storage facility 666.

The above-described functionality provided by software 616 is applied to an earlier electrocardiogram and thereafter to an later test electrocardiogram. The stored results for both of the test signals are supplied to software 619.

Software 619 preferably comprises comparison functionality 130 (Fig. 2), here designated by reference numeral 670, which compares the electrocardiogram analysis data relating to an actual test, stored by recording and storage facility 660 with earlier derived electrocardiogram analysis data also stored by facility 660 and preferably also with expected values for such electrocardiogram analysis data which may be received from database 138 (Fig. 2) here designated by reference numeral 671.

The comparison functionality 670 preferably provides comparison of measured and predicted values of various electrocardiogram parameters such as measured ECG parameters for each lead, typically including the heart rate, the R-R

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interval, P-P interval, P-R interval and Q-S interval as well as various relevant calculated ECG parameters

The comparison functionality 670 preferably applies sensed differences therebetween to thresholding functionality 132 which may apply a threshold to the comparison result indicating whether the currently sensed electrocardiogram parameters are substantially different from the previous or otherwise expected values therefor. Threshold functionality may employ data received from a personal database 671, which may also provide data to signal analysis functionality 664 of software 616 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 670 and thresholding functionality 672 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 674, which provides a description of the sensed electrocardiogram indications via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1).

Outputs provided by comparison functionality 670, thresholding functionality 672 and condition description functionality 674 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 676, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

Preferably, both condition description functionality 674 and recommendation functionality 676 also receive reference data from database 671.

Preferably, both condition description functionality 674 and recommendation functionality 676 receive reference data from a database 140, here designated by reference numeral 680, which stores acceptable ranges of outputs of comparison functionality 670, normalized for age and possibly other characteristics. Database 680 is preferably employed to enable condition description functionality 674 and recommendation functionality 676 to take into account the variation in acceptable changes in various personal parameters due to variations in age and possibly other characteristics.

Communication with a remote computer, such as a controller computer 16 (Fig. 1) may be initiated automatically by the general purpose computer 614 via the

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network 14, for example in response to the output of comparison functionality 670, threshold functionality 672, condition description functionality 674 or recommendation functionality 676, indicating, for example a possibly acute cardiac condition or a suspected misuse or malfunction of the kit.

Thus, when one or more sensed electrocardiogram parameters or the comparison output lies beyond a certain threshold which may indicate either an emergency situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 614 and the controller computer 620 via the network 14 (Fig. 1). Communication via the network 14 with the controller computer 620 may also be initiated by a user, at the user's initiative.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. It may be possible for medical personnel in the manned center 36 to directly view the patient while viewing the electrocardiogram directly and speaking with the user.

In accordance with a preferred embodiment of the present invention, the normal limits used in the threshold and condition description functionality may be established by medical personnel in the manned center 36 in accordance with the personal characteristics of each given patient.

Reference is now made to Fig. 7D, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5D and 6D.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a electrocardiogram test kit including a 3 - 4 lead ECG recorder/transmitter 610 and download of operating software to the user's general purpose computer 614 (Fig. 5D) from the controller computer 620 (Fig. 5D) or otherwise.

The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database 202 stores personal details of each patient for which the electrocardiogram kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the electrocardiogram sensing kit, to the extent that such results are

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transmitted to the controller computer 620. Preferably, the information entered by the user into the user records database 202 of the controller computer 620 as well as personal details and general medical information such as results of the tests conducted on the patient, are stored in the personal database 671 of the user's general purpose computer 614.

When the user is ready to perform an electrocardiogram test, following current use registration and calibration of the recorder/transmitter 610, a test is carried out as seen in Fig. 5D.

Software 619 provides appropriate signal processing and comparison of electrocardiogram indications received by the general purpose computer 614 from ECG recorder/transmitter 610. Software 619 preferably provides the following parameters:

Measured ECG parameters for each lead, such as the heart rate, R-R interval, P-P interval, P-R interval and Q-S interval.

Calculated ECG parameters which are relevant to disrhythmia.

It is appreciated that should one or more values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8D, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 614. Some or all of the parameters are preferably stored both at the user's general purpose computer 614 and in user records database 202 at the controller computer 620.

At a later time, when a test is carried out on the same patient all of the above listed parameters are analyzed and considered. Some of the above parameters are preferably normalized for the age of the patient.

The general purpose computer 614 preferably determines the differences between the earlier test values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

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Based on the calculated differences between the earlier and the current test results, and using the information contained in databases 671 and 680, the operating software installed at the user's general purpose computer 614 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 614 may also employ inputs from the controller computer 620 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 620 the comparison results and possibly some or all of the test information.

The controller computer may analyze the comparison results and possibly some or all of the test information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, the controller computer 620 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 620 may incur an additional charge, depending on the financial arrangements with the user.

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Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8D.

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The decision table of Fig. 8D is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 40 year male.

As noted above, based on the application of the decision and indication/recommendation functionality, an indication/recommendation such as "INSIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / NO ACTION REQUIRED", "POSSIBLY SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / ELECTROCARDIOGRAM DATA BEING TRANSFERRED TO CONTROLLER COMPUTER AND / OR MANNED CENTER FOR EVALUATION" and "SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / ELECTROCARDIOGRAM DATA BEING TRANSFERRED TO CONTROLLER COMPUTER AND / OR MANNED CENTER FOR EVALUATION / OBTAIN EMERGENCY TREATMENT IMMEDIATELY" may be made. In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 620 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources, such as pattern analysis, measuring P - P intervals and comparison thereof to R - R intervals. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician, may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 620 and the manned center are maintained at the controller computer 620 for future reference.

Turning to Fig. 8D, it is seen that for each of a plurality of relevant parameters, such as heart rate, R-R interval, Q/R ratio, P-P interval, P-R interval and Q-

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S interval normal limits as well as past and current test values are provided. Ratios may be calculated. Additionally or alternatively, the differences between a current test and previous tests and/or normal limits, as from databases 671 and 680, for the same patient may be determined and used. Software 619 (Fig. 5D) also includes a Holter monitoring software (24 hrs. ECG recording and monitoring) which analyses various parameters concerning disrhythmia such as concerning frequency of premature beats (PMB).

In this case independent weighting is preferably given both to the difference between current test values and baseline values and to the relationship between current test values and normal limits for such values. The differences and the relationships are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 620 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8D, four categories, each having a different weighting, are defined. Category A includes parameters typically having the ratio of the difference of current and baseline to the baseline measurements (D/B) of less than 20% and/or no premature beat (PMB), and is given a weight of 0. Category B includes parameters typically having a ratio of the difference of current and baseline to the baseline measurements (D/B) between 20% to 30% and/or up to 1 premature beat per minute (PMB) and is given a weight of 4. Category C includes parameters typically having the ratio of the difference of current and baseline to the baseline measurements (D/B) of more than 30% and/or more than 1 premature beat per minute (PMB) and is given a weight of 9. Category D includes situations wherein any of the parameters exceed normal limits or frequency of premature beats preferably according to physician's decision, and is given a weight of 4.

It is appreciated that in this example, an important criterion is the number of premature heart beats that occur in a unit of time.

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Thus it is seen in Fig. 8D that the Heart Rate falls within Category A and the P - P interval and P - R the interval fall within Category B. The Q - T interval falls within Category D. No parameters fall within Category C. The resulting total weighted score is thus 17.

The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8D, is typically as follows:

Weighted Score Indication/Recommendation

0 - 2 "INSIGNIFICANT CHANGE IN ELECTROCARDIOGRAM/NO ACTION RE-

QUIRED"

3 - 8 "POSSIBLY SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / ELEC-

TROCARDIOGRAM DATA BEING TRANSFERRED TO CONTROLLER COMPU-

TER AND / OR MANNED CENTER FOR EVALUATION"

9 + "SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM/ ELECTROCARDIO-

GRAM DATA BEING TRANSFERRED TO CONTROLLER COMPUTER AND/OR

MANNED CENTER FOR EVALUATION / OBTAIN EMERGENCY TREATMENT

IMMEDIATELY"

Accordingly, the recommendation in the example of Fig. 8D is "SIGNIFICANT CHANGE IN ELECTROCARDIOGRAM / ELECTROCARDIO-GRAM DATA BEING TRANSFERRED TO CONTROLLER COMPUTER AND/OR MANNED CENTER FOR EVALUATION / OBTAIN EMERGENCY TREATMENT IMMEDIATELY".

In this example, if the total exceeds typically 17, the manned center 36 is immediately invoked.

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Reference is now made to Fig. 5E, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for cardiac output measurement. Fig. 5E shows three stages in cardiac output measurement, a first stage, indicated by designation I, at which calibration takes place; an optional second stage, indicated by designation II, at which a baseline reference is generated and a third stage, indicated by designation III, at which an actual test is conducted. The context of Fig. 5E is typically a situation wherein a person has a heart condition and wishes to monitor any changes in his cardiac output.

In the environment of Fig. 5E, a user interface is provided which preferably includes a pair of wrist sensors 710, such as optical sensors commercially available from Triphase Medical Ltd. of Herzlia, Israel. The wrist sensors 710 typically provides an electrical output typically via interface circuitry 712 to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 714. Alternatively sensors 710 may be sensors which receive biometric inputs from locations other than the wrist.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 716, at general purpose computer 714 is operative for recording and storing calibration data and at least one baseline plot of cardiac output received by the general purpose computer 714 from wrist sensors 710.

Prior to generating a baseline plot of cardiac output, the wrist sensors 710 are calibrated, as indicated at I in Fig. 5E. A container 717, typically containing a column of water of a known height, typically 40 cm., is employed to calibrate software contained in the user's general purpose computer 714. The altitude at which the test takes place is normally not considered, up to altitudes of 1500 meters. Alternatively or additionally, calibration may be provided without the use of a column of water, by means of sensing biometric inputs. Such calibration functionality may be incorporated in either or both of sensors 710 and interface circuitry 712.

Following calibration of the output of the wrist sensors 710, a baseline plot may be generated by carrying out a baseline test, as seen at II in Fig. 5E. This baseline test is preferably carried out when the person shows no symptoms of cardiac distress. The baseline result may include measured blood oxygen saturation and calculated blood

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pressure and cardiac output volume. Preferably both the baseline test and all subsequent tests are carried out under identical conditions of cardiac stress. Most preferably, all tests are carried out when the subject is in a state of complete rest following at least 10 minutes of no activity.

Software 42 (Fig. 1), here designated by reference numeral 719, which is preferably resident in general purpose computer 714, provides appropriate signal processing and comparison of cardiac output indications received by the general purpose computer 714 from wrist sensors 710. Software 719 preferably provides an indication of calculated blood pressure and cardiac output volume.

Following establishment of the baseline reference, an actual test is carried out at a subsequent time, as indicated at III in Fig. 5E. The actual test is preferably carried out when the person senses that his cardiac output may have changed. It is seen that the test results for the actual test, shown at III, differ from the test results for the baseline reference, shown at II.

Software 719 compares the cardiac output received during the actual test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 719 typically provides, via the general purpose computer 714, an indication of exceedance or non-exceedance of the threshold along with a suitable description of the situation which may be accompanied by recommendations for action.

Software 719 typically compares calculated blood pressure and cardiac output volume.

A controller computer 16 (Fig. 1), here designated by reference numeral 720, preferably communicates with software 719 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the cardiac output may also be provided to the user. To enhance the efficacy of interface between the user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 722, may be located at the user location to enable personnel in the manned center 36 to view the patient who may be experiencing cardiac distress.

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In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 720, for example in response to cardiac output of a certain type or the output of a comparison of the currently sensed cardiac output with a baseline or with a standard reference which exceeds a threshold indicating a possibly critical condition or possibly improper use of the kit.

Reference is now made to Fig. 6E, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5E, namely cardiac output measurement, typically in an environment wherein a person wishes to monitor his cardiac output.

In the environment of Fig. 5E, as illustrated in Fig. 6E, wrist sensors 710 provides a pulse volume waveform via interface circuitry 712 (Fig. 5E) to recording and storage facility 716 (Fig. 5E) of general purpose computer 714 (Fig. 5E). As noted above with reference to Fig. 5E, preferably a baseline is initially established by a test conducted in an environment wherein a person is not in apparent cardiac distress. Thereafter, a further test may be conducted when the person has possible cardiac distress which is evidenced in the cardiac output parameters sensed during breathing. In both cases, the resulting waveform received from wrist sensors 710 is processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6E, interface circuitry 712 may be portable so as to be readily brought to the location of the patient and preferably employs a band pass filter 744 which filters out sounds picked up by the sensors 710 outside a desired band. The output of filter 744 is amplified by an amplifier 746 and preferably supplied to a memory 748. A portable power supply 752 preferably supplies power to the foregoing components as well as to a wireless communication interface 754 and/or a wired communication interface 756 which output to general purpose computer 714 (Fig. 5E).

In the embodiment of Fig. 6E, preferably the recording and storage facility 716 stores both baseline cardiac output data and actual test cardiac output data. A cardiac output waveform receipt and storage facility 760 receives and stores data received from interface 712. A signal processing facility 762 removes unwanted data artifacts and generally prepares the data for analysis.

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A signal analysis functionality 764 preferably performs the following functions on the cardiac output data:

For both the baseline and the actual test data, blood pressure and cardiac output volume are calculated.

The outputs of the signal analysis functionality 764 are preferably stored in storage facility 766.

The above-described functionality provided by software 716 is applied initially to a baseline signal and thereafter to an actual test signal. The stored results for both the baseline signal and for the test signal are supplied to software 719.

Software 719 preferably comprises comparison functionality 130 (Fig. 2), here designated by reference numeral 770, which compares the cardiac output analysis data relating to an actual test, stored by recording and storage facility 766, with baseline cardiac output analysis data also stored by facility 766 and preferably also with expected values for such cardiac output analysis data which may be received from database 138 (Fig. 2) here designated by reference numeral 771.

The comparison functionality 770 preferably provides comparison of blood pressure and cardiac output volume. It is appreciated that the functionality of Figs. 5E, 6E, 7E and 8E, using an non-invasive light sensor, is applicable as well to blood analysis such as determination of the hemoglobin level, blood sugar level, creatinine level and blood cholesterol level.

The comparison functionality 770 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference numeral 772, which may apply a threshold to the comparison result indicating whether the currently sensed cardiac output substantially different from the baseline and/or from the expected values therefor. Threshold functionality 772 may employ data received from a personal database 773, which may also provide data to signal analysis functionality 764 of software 716 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 770 and thresholding functionality 772 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 774, which provides a description of the sensed cardiac

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condition via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1).

Outputs provided by comparison functionality 770, thresholding functionality 772 and condition description functionality 774 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 776, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

It is appreciated that inasmuch as the functionality of Figs. 5E, 6E, 7E and 8E, using an non-invasive light sensor, is applicable to blood pressure and cardiac output as well to blood analysis such as determination of the hemoglobin level, blood sugar level, creatinine level and blood cholesterol level for healthy people as well as people having heart conditions, an appropriate set of recommendations may also be provided for normally healthy people. An example of application of this functionality to healthy people is that of fitness monitoring.

In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Preferably, both condition description functionality 774 and recommendation functionality 776 also receive reference data from database 771.

Preferably, both condition description functionality 774 and recommendation functionality 776 receive reference data from a database 140 (Fig. 2), here designated by reference numeral 780, which stores acceptable ranges of outputs of comparison functionality 770, normalized for age, weight, height, sex and possibly other characteristics. Database 780 is preferably employed to enable condition description functionality 774 and recommendation functionality 776 to take into account the variation in acceptable changes in various personal parameters due to variations in age, weight, height, sex and possibly other characteristics.

Communication with a remote computer, such as a controller computer 16 (Fig. 1) may be initiated automatically by the general purpose computer 714 via the

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network 14, for example in response to the output of comparison functionality 770, threshold functionality 772, condition description functionality 774 or recommendation functionality 776, indicating, for example a possibly acute respiratory condition or a suspected misuse or malfunction of the kit.

Thus, when one or more sensed cardiac output parameters or the comparison output lies beyond a certain threshold which may indicate either an emergency situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 714 and the controller computer 16 (Fig. 1) via the network 14 (Fig. 1). Communication via the network 14 with the controller computer 16 may also be initiated by a user, at the user's initiative.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. It may be possible for medical personnel in the manned center 36 to directly view the patient while hearing the cardiac output directly and speaking with the user.

Reference is now made to Fig. 7E, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5E and 6E.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a cardiac output test kit including wrist sensors 710, interface 712 and calibration container 717 (Fig. 5E) and download of operating baseline establishment software to the user's general purpose computer 714 (Fig. 5B) from the controller computer 720 (Fig. 5E) or otherwise.

The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database stores personal details of each patient for which the cardiac output sensing kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the cardiac output sensing kit, to the extent that such results are transmitted to the controller computer. Preferably, the information entered by the user into the user records database 202 of the controller computer 720 such as personal details and general medical information as well as results of the tests conducted on the patient, are stored in the personal database 771 of the user's general purpose computer 714.

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Calibration of the software in the user's general purpose computer 714 is preferably carried out by using container 717 to provide a calibrated pressure reference.

When the user is ready to perform a baseline establishing cardiac output test, following current use registration and calibration of the sensors 710, a baseline test may be carried out as seen at II in Fig. 5E.

Software 719 provides appropriate signal processing and comparison of cardiac output indications received by the general purpose computer 714 from wrist sensors 710. Software 719 preferably provides an indication of blood pressure and cardiac output as well possibly blood analysis information such as determination of the hemoglobin level, blood sugar level, creatinine level and blood cholesterol level for healthy people as well as people having heart conditions.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8E, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 714.

At a later time, when a test is carried out on the same patient, preferably all of the above listed parameters are measured and analyses are performed.

The general purpose computer 714 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 771 and 780, the operating software installed at the user's general purpose computer 714 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 714 may also employ inputs

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from the controller computer 720 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 720 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, the controller computer 720 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 720 may incur an additional charge, depending on the financial arrangements with the user.

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Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8E.

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The decision table of Fig. 8E is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 37 year male of height 172 cm and weight 67 kg.

As noted above, based on the application of the decision and indication/recommendation functionality, an indication/ recommendation such as "INSIGNIFICANT CHANGE IN CARDIAC PARAMETERS / NO ACTION REQUIRED", "SLIGHT CHANGE IN CARDIAC PARAMETERS / CONTACT PHYSICIAN / REPEAT TEST", "SIGNIFICANT CHANGE IN CARDIAC PARAMETERS / CONTACT PHYSICIAN IMMEDIATELY" may be made.

In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 720 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 720 and the manned center are maintained at the controller computer 720 for future reference.

Turning to Fig. 8E, it is seen that a plurality of relevant parameters, such as blood pressure and cardiac output may be measured and possibly also blood analysis information such as the hemoglobin level, blood sugar level, creatinine level and blood cholesterol level, may be determined. Additionally or alternatively, the differences between a current test and previous tests and/or predicted values, as from databases 771 and 780, for the same patient may be determined and used.

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The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 720 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8E, four categories, each having a different weighting, are defined. Category A includes parameters having a ratio of the difference of current and baseline to the baseline measurements (D/B) typically less than 10% and is given a weight of 0. Category B includes D/B ratio typically having a variation of more than 10% and less than 20% and is given a weight of 2. Category C includes parameters typically having a D/B ratio of more than 20% and is given a weight of 4. Category D includes situations wherein any of the parameters exceed normal limits, preferably according to physician's decision, and is given a weight of 8.

Thus it is seen in Fig. 8E that the heart rate falls within Category A and the blood pressure also falls within Category A. The cardiac output falls within Category D. No parameters fall within Category C. The resulting total weighted score is thus 8.

The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8E, is typically as follows:

Weighted Score Indication/Recommendation

0 - 3 "INSIGNIFICANT CHANGE IN CARDIAC OUTPUT / NO ACTION RE-

QUIRED"

4 - 8 "SLIGHT CHANGE IN CARDIAC PARAMETERS / CONTACT PHYSICIAN

/ REPEAT TEST"

9 + "SIGNIFICANT CHANGE IN CARDIAC PARAMETERS / CONTACT PHY-

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SICIAN IMMEDIATELY"

Accordingly, the recommendation in the example of Fig. 8E is "SLIGHT CHANGE IN CARDIAC PARAMETERS / CONTACT PHYSICIAN / REPEAT TEST".

Reference is now made to Fig. 5F, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for hearing testing, referred to hereinafter as audiometry. Fig. 5F shows three stages in audiometry, a first stage, indicated by designation I, at which calibration takes place; an optional second stage, indicated by designation II, at which a baseline reference is generated and a third stage, indicated by designation III, at which an actual test is conducted.

The context of Fig. 5F is typically a situation wherein a person wishes to test his hearing. In the environment of Fig. 5F, a user interface is provided which preferably includes a headset 810 and an optional response button 811, shown at stage I. A calibrator 812, such as a Model BA-201 or a Model BA 201-25 Bio-Acoustic Simulator, commercially available from Quest Technologies of Oconomowoc, U.S.A., which responds to predetermined sound amplitudes at predetermined frequencies is preferably provided. The headset 810 may be coupled directly to a conventional sound card of a general purpose computer 10 (Fig. 1), here designated by reference numeral 814. The calibrator 812 is operative to calibrate the sound card.

Preferably, the optional response button 811 is coupled to a serial port of computer 814. The response button may be obviated, such as by use of an Enter key. The response button 811 typically provides an electrical output to general purpose computer 814 which is preferably loaded with audiometry software 815, preferably ASAM 101, which is commercially available from Bar Advanced Control Systems Ltd. of Even Yehuda, Israel. This software provides much of the functionality described hereinbelow.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 816, at general purpose computer 814 is preferably provided by the audiometry software 815 and is operative for recording and storing calibration data and at least one baseline audiogram, typically a plot of a person's hearing threshold at various frequencies, such as 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz and 8000Hz.

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Prior to generating a baseline audiogram, the sound card is calibrated, as indicated at I in Fig. 5F for the specific headset 810 which is employed.

Following calibration of the sound card, a baseline audiogram is generated by carrying out a baseline test, as seen at II in Fig. 5F. The baseline result is a plot of a person's hearing threshold at various frequencies, such as 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz and 8000Hz as well as a calculated value of the average hearing threshold of a person within the frequency range of human speech, typically 500Hz - 3000Hz.

Software 42 (Fig. 1), here designated by reference numeral 819, which is preferably part of the audiometry software 815 resident in general purpose computer 814, provides appropriate signal processing and comparison of audiogram data received by the general purpose computer 814. Software 819 preferably provides an indication of the average hearing threshold of a person within the frequency range of human speech, typically 500Hz - 3000Hz.

Following establishment of the baseline reference, an actual test is carried out at a subsequent time, as indicated at III in Fig. 5F. It is seen that the test results for the actual test, shown at III, differ from the test results for the baseline reference, shown at II.

Software 819 compares the audiogram received during the actual test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 819 typically provides, via the general purpose computer 814, an indication of exceedance or non-exceedance of the threshold along with a suitable description of the situation which may be accompanied by recommendations for action.

Software 819 typically indicates changes the hearing threshold of a person, typically expressed in dB, as a function of the frequency of an audio input as indicated by tests taken at different times.

A controller computer 16 (Fig. 1), here designated by reference numeral 820, preferably communicates with software 819 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the audiogram also be provided to the user. To enhance the efficacy of

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interface between the user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 822, may be located at the user location to enable personnel in the manned center 36 to view the person undergoing testing.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 820, for example in response to audiogram of a certain type or the output of a comparison of the currently sensed audiogram with a baseline or with a standard reference which exceeds a threshold indicating a serious problem or possibly improper use of the kit.

Reference is now made to Fig. 6F, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5F, namely audiometry.

In the environment of Fig. 5F, as illustrated in Fig. 6F, an audiogram is provided to recording and storage facility 816 (Fig. 5F) of general purpose computer 814 (Fig. 5F). As noted above with reference to Fig. 5F, preferably a baseline is initially established. Thereafter, a further test is conducted. In both cases, the resulting audiogram is processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6F, preferably the recording and storage facility 816 stores both baseline audiogram data and actual test audiogram data. A audiogram receipt and storage facility 860 receives and stores audiogram data. A signal processing facility 862 removes unwanted data artifacts and generally prepares the data for analysis.

A signal analysis functionality 864 preferably performs the following functions on the audiogram data:

calculation of the average hearing threshold of a person within the frequency range of human speech, typically 500Hz - 3000Hz;

calculation of the average hearing threshold of a person within the frequency range of human speech, typically 4000Hz - 8000Hz;

indication of the difference, if any, between the aforesaid two average hearing thresholds; and

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indication of the rate of change in the hearing threshold as a function of frequency between 2000Hz and 4000Hz.

The outputs of the signal analysis functionality 864 are preferably stored in storage facility 866.

The above-described functionality provided by software 816 is applied initially to a baseline signal and thereafter to an actual test signal. The stored results for both the baseline signal and for the test signal are supplied to software 819.

Software 819 preferably comprises comparison functionality 130 (Fig. 2), here designated by reference numeral 870, which compares the audiogram analysis data relating to an actual test, stored by recording and storage facility 866 with baseline audiogram analysis data also stored by facility 866 and preferably also with expected values for such audiogram analysis data which may be received from database 138 (Fig. 2) here designated by reference numeral 871.

The comparison functionality 870 preferably provides comparison of measured, predicted and baseline values of various audiogram parameters such as:

the hearing threshold at each of a plurality of frequencies;

the average hearing threshold at each of a plurality of frequency ranges; and

the rate of change of the hearing threshold as a function of frequency.

The comparison functionality 870 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference numeral 872, which may apply a threshold to the comparison result indicating whether the currently sensed audiogram is substantially different from the baseline and/or from the expected values therefor. Threshold functionality 872 may employ data received from personal database 871, which may also provide data to signal analysis functionality 864 of software 816 for use in normalizing analysis data for given parameters of various persons.

Outputs of comparison functionality 870 and thresholding functionality 872 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 874, which provides a description of the audiometry condition via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1). Outputs provided by comparison functionality 870, thresholding functionality

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872 and condition description functionality 874 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 876, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

Preferably, both condition description functionality 874 and recommendation functionality 876 also receive reference data from database 880.

Preferably both condition description functionality 874 and recommendation functionality 876 receive reference data from a database 140 (Fig. 2), here designated by reference numeral 880, which stores acceptable ranges of outputs of comparison functionality 870, normalized for age and possibly other characteristics. Database 880 is preferably employed to enable condition description functionality 874 and recommendation functionality 876 to take into account the variation in acceptable changes in various personal parameters due to variations in age and possibly other characteristics.

Communication with a remote computer, such as a controller computer 820, may be initiated automatically by the general purpose computer 814 via the network 14, for example in response to the output of comparison functionality 870, threshold functionality 872, condition description functionality 874 or recommendation functionality 876, indicating, for example a possibly acute auditory condition or a suspected misuse or malfunction of the kit.

Thus, when one or more sensed audiogram parameters or the comparison output lies beyond a certain threshold which may indicate a situation requiring controller intervention, communication is established between the user's general purpose computer 814 and the controller computer 820 via the network 14 (Fig. 1). Communication via the network 14 with the controller computer 16 may also be initiated by a user, at the user's initiative.

The controller computer 820 typically compares the audiogram to various known reference audiograms, including, for example reference audiograms indicating phonal trauma.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. It may be possible for medical personnel in

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the manned center 36 to directly view the patient while hearing the audiogram directly and speaking with the user.

Reference is now made to Fig. 7F, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5F and 6F.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a audiogram test kit including headset 810, response button 811 and calibrator 812 (Fig. 5F) and download of operating audiometry software 815 to the user's general purpose computer 814 (Fig. 5F) from the controller computer 820 (Fig. 5F) or otherwise.

The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database stores personal details of each patient for which the audiometry kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the audiogram sensing kit, to the extent that such results are transmitted to the controller computer. Preferably, the information entered by the user into the user records database 202 of the controller computer 820 such as personal details and general medical information as well as results of the tests conducted on the patient, are stored in the personal database 871 of the user's general purpose computer 814.

When the user is ready to perform a baseline establishing audiogram test, following current use registration and calibration, a baseline test is carried out as seen at II in Fig. 5F.

Software 819 provides appropriate signal processing and comparison of audiogram data received by the general purpose computer 814.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8F, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

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At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 814.

The general purpose computer 814 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 871 and 880, the operating software installed at the user's general purpose computer 814 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 814 may also employ inputs from the controller computer 820 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 820 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, a duly certified physician at the manned center 36 confirms the comparison results and signs a report, which may be required by governmental or other authorities. The physician signature may be effected electronically in a conventional manner.

Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8F.

The decision table of Fig. 8F is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 37 year male.

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As noted above, based on the application of the decision and indication/recommendation functionality, an indication/ recommendation such as "INSIGNIFICANT CHANGE IN AUDIOGRAM / NO ACTION REQUIRED", "POSSIBLY SIGNIFICANT CHANGE IN AUDIOGRAM / REPEAT TEST" and "SIGNIFICANT CHANGE IN AUDIOGRAM / CONSULT PHYSICIAN" may be made. In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 820 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 820 and the manned center are maintained at the controller computer 820 for future reference.

Turning to Fig. 8F, it is seen that for each of a plurality of relevant parameters, such as:

the hearing threshold at each of a plurality of frequencies;

the average hearing threshold at each of a plurality of frequency ranges; and

the rate of change of the hearing threshold as a function of frequency, predicted, baseline and current test values are provided. Ratios may be calculated. Additionally or alternatively, the differences between a current test and previous tests and/or predicted values, as from databases 871 and 880, for the same patient may be determined and used.

In Fig. 8F, "slope" is measured on a standard audiogram graph according to the OSHA USA standard.

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The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 820 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8F, three categories, each having a different weighting, are defined. Category A includes parameters having a ratio of the difference of current and baseline to the baseline measurements (D/B) less than 25% and is given a weight of 0. Category B includes parameters having a D/B value of more than 25% and is given a weight of 4. Category C includes parameters exceeding normal limits, preferably according to physician's decision, and is given a weight of 6.

It is appreciated that differences in different parameters may be measured in different ways, as most appropriate. In the example of Fig. 8E, however, the differences in all parameters are all measured as the ratio of current to baseline values.

Thus it is seen in Fig. 8F that no parameter falls within Category A and three parameters, namely:

the average hearing threshold of a person within the frequency range of human speech, typically 500Hz - 3000Hz;

the average hearing threshold of a person within the frequency range of human speech, typically 4000Hz - 8000Hz;

the rate of change in the hearing threshold as a function of frequency between 2000Hz and 4000Hz, fall within category B.

Two parameters, namely:

the average hearing threshold of a person within the frequency range of human speech, typically 4000Hz - 8000Hz;

the rate of change in the hearing threshold as a function of frequency between 2000Hz and 4000Hz, fall within category C. The resulting total weighted score is thus 24.

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The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8E, is typically as follows:

Weighted Score	Indication/Recommendation
0 - 5	"INSIGNIFICANT CHANGE IN AUDIOGRAM / NO ACTION REQUIRED"
6 - 12	"POSSIBLY SIGNIFICANT CHANGE IN AUDIOGRAM / REPEAT TEST"
13 +	"SIGNIFICANT CHANGE IN AUDIOGRAM / CONSULT PHYSICIAN"

Accordingly, the recommendation in the example of Fig. 8F is "SIGNIFICANT CHANGE IN AUDIOGRAM / CONSULT PHYSICIAN".

Reference is now made to Fig. 5G, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for skin condition sensing. Fig. 5G shows skin condition sensing at two different times, indicated by designations I and II, which enable analysis of progression of the skin condition. This type of sensing is appropriate for both acute conditions, such as allergic reasons, chicken pox and measles and chronic conditions such as acne and nevus, some of which could possibly progress to melanoma. The context of Fig. 5G is typically a situation wherein a person, such as a child, has a visually apparent skin condition.

In the environment of Fig. 5G, a user interface is provided which preferably includes a digital or video camera 910. A suitable camera which is provided together with skin lesion comparison software is commercially available from Romedix Ltd. of Ramat Gan, Israel under the trademark Nevuscan. The camera 910 provides an electrical output to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 914.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 916, at general purpose computer 914 is operative for recording and storing at least one image of skin received by the general purpose computer 914 from camera 910 during at least one first test taken at least a first time, such as on June 30, 1999. This first test is preferably carried out when the patient, such as a child, has a visible skin

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condition. and may be employed to establish a baseline. The baseline result may be visualized by a representation 917.

Software 42 (Fig. 1) here designated by reference numeral 918, which is preferably resident in general purpose computer 914, provides appropriate signal processing and comparison of skin condition representations received by the general purpose computer 914 from camera 910 during a subsequent test taken at a subsequent time, such as on August 15, 1999. This second test is preferably carried out when the child continues to show symptoms of the skin condition and may require attention. It is seen that the representation 919 differs from previous representation 917.

Software 918, which preferably is at least partially embodied in software supplied with the aforesaid Nevuscan product, compares the skin representations during the second test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 918 typically provides, via the general purpose computer 914, an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 918 typically compares various skin lesion parameters such as: size, shape, circumference, color, color variation, uniformity, texture and sharpness of the transition between the skin lesion and the surrounding skin.

A controller computer 16 (Fig. 1), here designated by reference numeral 920, preferably communicates, via the network 930, with software 918 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the skin may also be provided to the user. To enhance the efficacy of interface between the user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 922, may be located at the user location to enable personnel in the manned center 36 to view the patient.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 920, for example in response to skin condition of a certain type or the output of a comparison of the currently sensed

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skin condition with a baseline or with a standard reference which exceeds a threshold indicating a possibly critical condition or possibly improper use of the kit.

Reference is now made to Fig. 6G, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5G, namely skin condition sensing, typically in an environment wherein a person, such as a child, has a skin condition.

In the environment of Fig. 5G, as illustrated in Fig. 6G, camera 910 provides an image of an area of skin to recording and storage facility 916 (Fig. 5G) of general purpose computer 914 (Fig. 5G). As noted above with reference to Fig. 5G, preferably a baseline is initially established. Thereafter, at an appropriate later time a further test may be conducted. In both cases, the resulting image received from camera 910 is processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6G, preferably, the recording and storage facility 916 stores both baseline skin image data and later test skin image data. A skin image signal receipt and storage facility 960 receives and stores the signal received from camera 910. A signal processing facility 962 removes unwanted signal artifacts and generally prepares the signal for analysis.

A signal analysis functionality 964 preferably includes at least part of the skin lesion comparison software commercially available from Romedix Ltd. of Ramat Gan, Israel under the trademark Nevuscan and preferably performs the following functions on the skin signals:

Determination of area of skin lesions;

Determination of shape of skin lesions;

Determination of circumference of skin lesions;

Determination of color of skin lesions;

Determination of color variation of skin lesions;

Determination of uniformity of skin lesions;

Determination of texture of skin lesions; and

Determination of sharpness of the transition between the skin lesion and the surrounding skin;

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Normalization of the above parameters for the age or other characteristics, using patient data from a personal database, typically forming part of software 918.

The outputs of the signal analysis functionality 964 for the signal are preferably stored in storage facility 966.

The above-described functionality provided by software 916 preferably is applied initially to baseline data and thereafter to further test data. The stored results for both baseline and further tests are supplied to software 918.

Comparison functionality 130 (Fig. 2), here designated by reference numeral 970, which is included in software 918 (Fig. 5G), compares the skin image and analysis data relating thereto stored by recording and storage facility 916 with a baseline skin image and analysis data relating thereto, also stored by facility 916. Comparison functionality 970 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference numeral 972, which may apply a threshold to the comparison result indicating whether the currently sensed skin image data is substantially different from the baseline. Threshold functionality may employ data received from a personal database 974, which may also provide data to signal analysis functionality 964 of software 916 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 970 and thresholding functionality 972 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 975, which provides a description of the sensed respiratory condition via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1). Outputs provided by comparison functionality 970, thresholding functionality 972 and condition description functionality 975 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 976, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

Preferably, both condition description functionality 975 and recommendation functionality 976 receive reference data from a database 140 (Fig. 2), designated by reference numeral 980, which stores acceptable ranges of outputs of comparison functionality 970, normalized for age and possibly other characteristics. Database 980 is

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preferably employed to enable condition description functionality 975 and recommendation functionality 976 to take into account the variation in acceptable changes in various personal parameters due to variations in age and possibly other characteristics.

Communication with a remote computer, such as a controller computer 16 (Fig. 1) is preferably initiated automatically by the general purpose computer 914 via the network 14, for example in response to the output of comparison functionality 970, threshold functionality 972, condition description functionality 975 or recommendation functionality 976, indicating, any medically significant change in the skin lesion.

Thus, when a sensed skin parameter or the comparison output lies beyond a certain threshold which may indicate a medically significant skin event, communication is established immediately between the user's general purpose computer 914 and the controller computer 16 (Fig. 1) via the network 14 (Fig. 1). Communication via the network 14 with the controller computer 920 may also be initiated by a user, at the user's initiative. This communication enables reference data to be readily accesses for evaluation of the skin event.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. It may be possible for medical personnel in the manned center 36 to directly view the patient while hearing and speaking with the user.

Reference is now made to Fig. 7G, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5G and 6G.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a skin examination test kit including a camera such as camera 920 and download of operating software to the user's general purpose computer 914 (Fig. 5G) from the controller computer 920 (Fig. 5G) or otherwise. The user registers with the user records database 202 of the controller computer (Fig. 3). As noted above, the user records database stores personal details of each patient for which the skin sensing kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the skin sensing kit, to the extent that such

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results are transmitted to the controller computer. Preferably, the information entered by the user into the user records database of the controller computer 920 is also stored in the user's general purpose computer 914. Thus, such as the personal details and general medical information as well as results of the tests conducted on the patient, are stored in the personal database 974 of the user's general purpose computer 914.

When the user is ready to perform a baseline establishing skin test, following current use registration, a baseline determination is carried out typically in the following manner:

The skin image data is recorded at the user's general purpose computer 914.

As noted above, the following determinations are made with respect to detected skin lesions:

Determination of area of skin lesions;

Determination of shape of skin lesions;

Determination of circumference of skin lesions;

Determination of color of skin lesions;

Determination of color variation of skin lesions;

Determination of uniformity of skin lesions;

Determination of texture of skin lesions; and

Determination of sharpness of the transition between the skin lesion and the surrounding skin.

At least some of the above parameters are preferably normalized for the age of the patient.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8G, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

At a later time, when a test is carried out on the same patient preferably all of the above listed parameters are measured and analyses are performed. Some of the above parameters are preferably normalized for the age of the patient.

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At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 914. Some or all of the parameters are preferably stored both at the user's general purpose computer 914 and in user records database 202 at the controller computer 920.

The general purpose computer 914 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 974 and 980, the operating software installed at the user's general purpose computer 914 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 914 may also employ inputs from the controller computer 920 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 920 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

Preferably, the controller computer 920 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 920 may incur an additional charge, depending on the financial arrangements with the user.

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Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8G.

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The decision table of Fig. 8G is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical patient, a 10 year child having skin lesions over two weeks.

As noted above, based on the application of the decision and indication/recommendation functionality, indications/recommendations such as "INSIGNIFICANT CHANGE IN SKIN LESION / NO ACTION REQUIRED", "SIGNIFICANT CHANGE IN SKIN LESION / CONSULT PHYSICIAN" may be made. In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 920 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources, such as a library of images of skin lesions indicating the procession thereof. The controller computer preferably provides a basis for diagnosis based on similarity of the sensed patient skin image data to image data stored in the library and may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between the user and both the controller computer 920 and the manned center are maintained at the controller computer for future reference.

Turning to Fig. 8G, it is seen that for each of a plurality of relevant skin lesion parameters, such as: size, shape, circumference, color, color variation, uniformity and texture, baseline and current test values are provided. Ratios and differences are calculated. Additionally or alternatively, the differences between a current test and previous tests and/or predicted values, as from databases 974 and 980, for the same patient may be determined and used.

The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that

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various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 920 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8G, three categories, each having a different weighting, are defined. Category A includes parameters having a ratio of the difference of current and baseline to the baseline measurements (D/B) less than 20% and is given a weight of 0. Category B includes parameter D/B with value more than 20% and is given a weight of 4. Category C includes parameters which fall within pathological patterns as indicated in a stored reference library and is given a weight of 6.

It is appreciated that differences in different parameters may be measured in different ways, as most appropriate. In the example of Fig. 8G, however, the differences in all parameters are all measured as the ratio of current to baseline values.

Thus it is seen in Fig. 8G that no parameter falls within Category A and two parameters, namely area and circumference of skin lesions, fall within category B.

Two parameters, namely uniformity of skin lesions and sharpness of the transition between the skin lesion and the surrounding skin, fall within category C. The resulting total weighted score is thus 20.

The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8G, is typically as follows:

Weighted Score	Indication/Recommendation
0 - 6	"INSIGNIFICANT CHANGE IN SKIN LESIONS / NO ACTION RE-QUIRED"
7 +	"SIGNIFICANT CHANGE IN SKIN LESIONS / CONSULT PHYSI-CIAN"

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Accordingly, the recommendation in the example of Fig. 8G is "SIGNIFICANT CHANGE IN SKIN LESIONS / CONSULT PHYSICIAN". As indicated above, preferably, the reference library is employed to provide evaluation of the skin lesion and comparison thereof to known lesions.

Reference is now made to Fig. 5H, which is a pictorial illustration of part of the medical condition sensing system of Fig. 1 being employed for vision sensing. The context of Fig. 5H is typically a situation wherein a person is having his vision tested.

In the environment of Fig. 5H, a user interface is provided which preferably includes a vision testing headset 1010, such as a virtual reality headset, typically a V8 Head Mount Display, commercially available from Virtual research Systems, Inc of Santa Clara, California, which is modified to permit ready replacement or displacement of lenses therein. The vision testing headset 1010 provides an electrical output typically via interface circuitry 1012, typically commercially available with the V8 Head Mount Display, to a suitable interface of a general purpose computer 10 (Fig. 1), here designated by reference numeral 1014.

A recording and storage facility 40 (Fig. 1), here designated by reference numeral 1016, at general purpose computer 1014 is operative for recording and storing at least one baseline plot of vision received by the general purpose computer 1014 from vision testing headset 1010 during at least one first test. Typical test results are shown at reference numeral 1017 on a display of the general purpose computer 1014.

Typically the test procedure involves presenting to the vision test in accordance with a commercially available test procedure, such as the AVAT test procedure developed by Bar Advanced Control Systems Ltd. of Even Yehuda, Israel, which is described in published PCT Patent Application WO 98/02083, preferably using the commercially available AVAT keyboard, which is also commercially available from Bar Advanced Control Systems Ltd. of Even Yehuda, Israel. Additionally or alternatively, commercially available speech recognition software can be used for receiving subject responses. AVAT software typically uses signals for determining visual acuity threshold such as "C" marks of different sizes, and indicated by reference numeral 1018 in Fig. 5H.

Software 42 (Fig. 1) here designated by reference numeral 1019, which typically includes software embodying the AVAT test procedure, which is preferably

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resident in general purpose computer 1014, provides appropriate signal processing and comparison of vision data received by the general purpose computer 1014 from vision testing headset 1010 during at least one subsequent test taken at a later time.

Software 1019 compares the vision data received during the second test with the baseline established by at least one earlier test and may apply a threshold to the comparison result. Software 1019 typically provides via the general purpose computer 1014 an indication of exceedance or non-exceedance of the threshold along with suitable description of the situation which may be accompanied by recommendations for action.

Software 1019 typically compares various vision parameters such as visual acuity at 40 cm, 80 cm and 600 cm, color vision, depth perception and phoria.

A controller computer 16 (Fig. 1), here designated by reference numeral 1020, preferably communicates, via the network 1021, with software 1019 for assisting in providing recommendations for action. Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation of the vision data may also be provided to the user. To enhance the efficacy of interface between the user and personnel in the manned center 36 (Fig. 1) a video camera 38 (Fig. 1), here designated by reference numeral 1022, may be located at the user location to enable personnel in the manned center 36 to view the patient who is experiencing apparent vision difficulties.

In accordance with another preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, normally through the action of the controller computer 1020, for example in response to vision of a certain type or the output of a comparison of the currently sensed vision with a baseline or with a standard reference which exceeds a threshold indicating vision difficulty or possibly improper use of the kit.

Reference is now made to Fig. 6H, which is a simplified functional block diagram of the system of Fig. 1 having the functionality of Fig. 5H, namely vision sensing.

In the environment of Fig. 5H, as illustrated in Fig. 6H, vision testing headset 1010 provides vision data via interface circuitry 1012 (Fig. 5H) to recording and storage facility 1016 (Fig. 5H) of general purpose computer 1014 (Fig. 5H). As noted above with reference to Fig. 5H, preferably a baseline is initially established by an earlier test. Thereafter, a further test may be conducted at an appropriate time. In

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both cases, the resulting vision data received from vision testing headset 1010 is processed using the functionality described hereinabove with reference to Figs. 2, 3 and 4.

In the embodiment of Fig. 6H, interface circuitry 1012 is preferably portable and preferably employs a band pass filter 1044 which filters out noise outside a desired band. The output of filter 1044 is amplified by an amplifier 1046 and preferably supplied to a memory 1048. A portable power supply 1052 preferably supplies power to the foregoing components as well as to a wireless communication interface 1054 and/or a wired communication interface 1056 which output to general purpose computer 1014 (Fig. 5H).

In the embodiment of Fig. 6H, preferably, the recording and storage facility 1016 stores both baseline vision data and later test vision data. A vision data receipt and storage facility 1060 receives and stores the data received from interface 1012. A signal processing facility 1062 removes unwanted signal artifacts and generally prepares the data for analysis.

Signal analysis functionality 1064 preferably performs the following functions on the vision data signals:

Determination of various vision parameters such as visual acuity at 40 cm, 80 cm and 600 cm;

Determination of color vision;

Determination of depth perception;

Determination of phoria.

Normalization of the above parameters may be carried out for the age and possibly other parameters of the patient, using patient data from a personal database 1074, typically forming part of software 1019.

The outputs of the signal analysis functionality 1064 for the vision data is preferably stored in storage facility 1066.

The above-described functionality is provided by facility 1016 and is applied initially to a baseline test and thereafter to subsequent tests. The stored results for both the baseline data and for the test data are supplied to software 1019.

Comparison functionality 130 (Fig. 2), here designated by reference numeral 1070, which is included in software 1019 (Fig. 5H), compares the vision data and analysis data relating thereto stored by recording and storage facility 1016 with baseline vision data and analysis data relating thereto, also stored by facility

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1016. Comparison functionality 1070 preferably applies sensed differences therebetween to thresholding functionality 132 (Fig. 2), here designated by reference numeral 1072, which may apply a threshold to the comparison result indicating whether the currently sensed vision parameters are substantially different from the baseline. Threshold functionality may employ data received from a personal database 1074, which may also provide data to signal analysis functionality 1064 of software 1016 for use in normalizing analysis data for given patient parameters.

Outputs of comparison functionality 1070 and thresholding functionality 1072 are preferably provided to condition description functionality 134 (Fig. 2) here designated by reference numeral 1075, which provides a description of the vision condition of the subject via an output device, such as a display 50, printer 52 and audio transducer 54 (Fig. 1). Outputs provided by comparison functionality 1070, thresholding functionality 1072 and condition description functionality 1075 may be further processed by recommendation functionality 136 (Fig. 2) here designated by reference numeral 1076, which may provide indications/recommendations to the user via any one or more of display 50, printer 52 or transducer 54.

Preferably, both condition description functionality 1075 and recommendation functionality 1076 receive reference data from a database 140 (Fig. 2), designated by reference numeral 1080, which stores acceptable ranges of outputs of comparison functionality 1070, normalized for age and possibly other characteristics. Database 1080 is preferably employed to enable condition description functionality 1075 and recommendation functionality 1076 to take into account the variation in acceptable changes in various vision parameters due to variations in age and possibly other characteristics.

Communication with a remote computer, such as controller computer 1020 may be initiated automatically by the general purpose computer 1014 via the network 14, for example in response to the output of comparison functionality 1070, threshold functionality 1072, condition description functionality 1075 or recommendation functionality 1076, indicating, for example a possibly acute vision condition or change therein or a suspected misuse of the kit.

Thus, when a sensed vision parameter or the comparison output lies beyond a certain threshold which may indicate either an acute situation or a situation requiring controller intervention, communication is established immediately between the user's general purpose computer 1014 and the controller computer 1020 via the

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network 14 (Fig. 1). Communication via the network 14 with the controller computer 1020 may also be initiated by a user, at the user's initiative.

Where a manned center 36 (Fig. 1) is provided, a human interface or human evaluation may also be provided to the user. the manned center 36 to view the test subject. It may be possible for medical personnel in the manned center 36 to directly view the patient while hearing the vision directly and speaking with the user.

Reference is now made to Fig. 7H, which is a simplified flowchart illustrating the operation of the system of Fig. 1 in the operative environment of Figs. 5H and 6H.

Initially the user accesses a system web site and carries out the initial communications and actions described hereinabove with respect to Fig. 4, which include the acquisition of a vision testing headset and download of operating baseline establishment software to the user's general purpose computer 1014 (Fig. 5H) from the controller computer 1020 (Fig. 5H) or otherwise. The user registers with the user records database 202 of the controller computer 1020 (Fig. 5H). As noted above, the user records database 202 stores personal details of each patient for which the vision sensing kit is to be used as well as general medical information regarding each such patient and results of tests conducted on that patient, using the vision sensing kit, to the extent that such results are transmitted to the controller computer. Preferably, the information entered by the user into the user records database 202 of the controller computer 1020 is also stored in the user's general purpose computer 1014. Thus, such as personal details and general medical information as well as the tests conducted on the patient, are stored in the personal database 1074 of the user's general purpose computer 1014.

When the user is ready to perform a baseline establishing vision test, following current use registration, a baseline determination is carried out typically in the following manner:

The vision data is recorded at the user's general purpose computer 1014.

The following determinations are preferably carried out at the user's general purpose computer:

Determination of various vision parameters such as visual acuity at 40 cm, 80 cm and 600 cm;

Determination of color vision;

Determination of depth perception;

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Determination of phoria.

Some of the above parameters are preferably normalized for the age and possibly other characteristics of the subject.

It is appreciated that should one or more baseline values differ from expected values to a medically significant extent, such as that described hereinbelow with reference to Fig. 8H, appropriate indications/recommendations may be provided immediately to the user and the controller computer and the manned center may be employed as appropriate.

At a later time, when a test is carried out on the same subject, preferably all of the above listed parameters are measured and analyses are performed. Some of the above parameters are preferably normalized for the age and possibly other characteristics of the patient.

At least some of the foregoing parameters as well as possibly other parameters are employed by operating software installed at the user's general purpose computer 1014. Some or all of the parameters are preferably stored both at the user's general purpose computer 1014 and in user records database 202 at the controller computer 1020.

The general purpose computer 1014 preferably determines the differences between the baseline values and the current test values for the various parameters and analysis results and preferably indicates both the absolute difference and the percentage difference.

Based on the calculated differences between the baseline and the current test results, and using the information contained in databases 1074 and 1080, the operating software installed at the user's general purpose computer 1014 is preferably operative to provide a condition description and recommendations to the user via the user's general purpose computer. The user's general purpose computer 1014 may also employ inputs from the controller computer 1020 in providing the condition description and recommendations to the user.

Depending on the comparison results and the recommendations, the user's computer may provide to the controller computer 1020 the comparison results and possibly some or all of the test and baseline information.

The controller computer may analyze the comparison results and possibly some or all of the test and baseline information and provide results of the analysis to the user via the user's general purpose computer.

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Preferably, the controller computer 1020 makes a determination as to whether to contact a manned center 36. The user may make an independent determination whether to contact the manned center 36. A user's decision to utilize the services of the manned center which is not supported by the decision of the controller computer 1020 may incur an additional charge, depending on the financial arrangements with the user.

Preferably, the condition description and recommendations are provided in accordance with a decision table, an example of which is provided in Fig. 8H.

The decision table of Fig. 8H is merely exemplary and illustrates the application of typical decision and recommendation functionality to a typical subject, a 40 year old male.

As noted above, based on the application of the decision and indication/recommendation functionality, an indication/ recommendation such as "VISION WITHIN ACCEPTABLE LIMITS", "CHANGE IN VISION FROM PREVIOUS EXAMINATION OR VISION OUTSIDE NORMAL LIMITS / CONTACT VISION PROFESSIONAL / REPEAT TEST" and "VISION NOT WITHIN ACCEPTABLE LIMITS / CONSULT VISION PROFESSIONAL".

In certain cases where the computer is unable to provide a reliable indication/recommendation due to technical difficulties with the test, an indication such as "BECAUSE OF TECHNICAL PROBLEMS RECOMMENDATION UNAVAILABLE / CONTACT YOUR PHYSICIAN / REPEAT TEST" may be provided.

Additionally or alternatively, an automatic connection may be made to the controller computer 1020 which may apply decision functionality similar to that used by the user's general purpose computer, but preferably including additional informational resources. The controller computer may also make any of the above-listed recommendations to the user. Alternatively or additionally, an automatic connection may be made to the manned center 36 (Fig. 1) wherein a human operator, such as a physician may review all of the personal parameters, analyses thereof and additional available medical information and make appropriate recommendations for action.

As noted above, complete records of all communications between both the user and the controller computer 1020 and the manned center 36 are maintained at the controller computer for future reference.

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Turning to Fig. 8H, it is seen that for each of a plurality of relevant parameters, such as visual acuity at 40 cm, 80 cm and 600 cm; color vision; depth perception and phoria. baseline and current test values are provided. Differences are calculated. Additionally or alternatively, the differences between a current test and previous tests, for the same subject may be determined and used.

The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted, value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 1020 and/or to engage the services of the manned center 36 (Fig. 1).

In the specific example shown in Fig. 8H, three categories, each having a different weighting, are defined. Category A includes parameters having a current to baseline (C/B) ratio less than 30% and is given a weight of 0. Category B includes parameters having a current to baseline (C/B) ratio above 30% and is given a weight of 8. Category C includes parameters which lie outside normal limits, preferably according to physician's decision, and is given a weight of 4.

It is appreciated that differences in different parameters may be measured in different ways, as most appropriate.

It is seen in Fig. 8H that two parameters, namely visual acuity at 40 cm and depth perception, fall within Category A no parameters fall within Category B. One parameter, namely visual acuity at 6 meters, falls within Category C. The resulting total weighted score is thus 4.

The relationship between weighted scores and indications/recommendations for the example shown in Fig. 8H is typically as follows:

Weighted Score Indication/Recommendation

0 - 3 "VISION WITHIN ACCEPTABLE LIMITS"

4 - 12 "CHANGE IN VISION FROM PREVIOUS EXAMINATION OR VISION

OUTSIDE NORMAL LIMITS / CONTACT VISION PROFESSIONAL / REPEAT TEST"

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13 + "VISION NOT WITHIN ACCEPTABLE LIMITS / CONSULT VISION

PROFESSIONAL".

Accordingly, the recommendation in the example of Fig. 8H is "CHANGE IN VISION FROM PREVIOUS EXAMINATION OR VISION OUTSIDE NORMAL LIMITS / CONTACT VISION PROFESSIONAL / REPEAT TEST"

Turning to Fig. 8H, it is seen that for each of a plurality of relevant parameters, baseline and current test values are provided. Absolute and percentage differences are calculated. Additionally or alternatively, the differences between a current test and previous tests, for the same subject be determined and used.

The differences are preferably categorized as to their significance and the number of parameters falling within each category are noted. It is appreciated that various parameters may be given different weighting. All of the relevant parameters are taken into account with their respective weighting and a total, suitably weighted value is used to determine which indications/recommendations are provided to the user and whether to utilize the analysis of the controller computer 1020 and/or to engage the services of the manned center 36 (Fig. 1).

The above embodiment has been described with reference to a number of specific applications. It is appreciated that the embodiment is not limited to those applications and that the invention may be used in many other applications. Some examples of additional applications include the following:

Heart sound monitoring, which may include functionality very similar to that of lung sound monitoring described hereinabove.

Fetal monitoring, which may involve sensing various biometric parameters, such as fetal ECG and Doppler of the fetal heart and umbilical cord artery, and differentiating those of the fetus from those of the mother. The fetal monitoring may also include monitoring contractions of the uterus.

Sleep apnea monitoring typically employing functionality very similar to that of lung sound monitoring described hereinabove.

Alertness monitoring, such as using a combination of biometric parameters, including, for example, posture monitoring, response speed monitoring, eye-hand coordination monitoring and eye tracking.

Reference is now made to Fig. 9a, which is a generalized diagram of a system that supports, through one or more central or distributed servers, a variety of

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data capturing, data exchange, data evaluation and data scoring activities between patients and their care providers. The patient may utilize a variety of devices to enter information and access the system, inclusive of: personal computer, computer, phone, cellular phone, PDA (Personal Digital Assistant), email, pager, medical sensors and others, in order to send information to the system and receive information from the system. The care provider may likewise use a variety of devices to configure and access the system, inclusive of: personal computer, computer, phone, cellular phone, PDA (Personal Digital Assistant), email, pager, medical sensors and others, in order to send information to the system and receive information from the system. The central server(s) enable secure capturing and processing of a variety of patient information, its processing and its distribution to the patients and care providers according to pre-defined rules configurable by a variety of potential authorized users.

In a first embodiment, the patient may be in possession of a data processing device capable of handling low complexity software. Such devices may include a data-enabled mobile telephone 2010 or a desktop computer 2012. The data processing device is preferably combined with a measuring device 2014 able to measure at least one type of body parameter such as pulse rate, blood pressure etc.

The data processing device 2010, 2012, is preferably able to process data input from the measuring device 2014, in a manner that will be described below, in order to give the patient an outcome such as a recommendation for action. Examples of the outcome may be instructions to the patient such as repeat the measurement at a certain time, or that the dosage of a treatment should be stepped up or down, or that the doctor should be contacted immediately, or any other outcome. As will be described below, the outcome is preferably defined by the physician or other care provider.

In an embodiment, the processing is carried out locally with the patient. In another embodiment no processing is carried out with the patient. Instead the measurement results are transferred using voice or tone over the telephone to a server 18 which takes in the information and processes it. It then issues a voice result to the patient. In addition, it may automatically alert the physician or other care provider or hospital or order an ambulance.

As another alternative, the data from the measurement apparatus may be added to a form at the local computer 2012 such as an HTML or XML form and the

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form may be processed either locally or remotely depending on the way the system is set up. Measurement data may be inserted into the form either manually using a keyboard or by a touch screen or by voice and voice processing or automatically by connecting the measurement device 2014 to the computer 2012, for example via the serial port. Again, such a system may automatically alert the physician or hospital or order an ambulance.

The system advantageously makes use of unified messaging so that the patient can send information via any messaging media. It may be more convenient in any given circumstances, to use the standard telephone network or fax or the Internet or any other type of available connection. A particular physician may set up the system so that patients having Internet are set up to use the Internet as the means of contacting a central server. Those that do not have an Internet connection use the telephone where a voice recognition system based on the server is able to take voice instructions and answer using voice, or where the telephone keypad is used for data entry.

Likewise from the physician's point of view, he may wish to be notified immediately of urgent patient conditions and thus would like calls to be put through to a pager or to his mobile telephone if he cannot be contacted at his surgery, office or home. When he can be contacted at his surgery, office or home he may prefer to be contacted via the Internet for most situations. For extremely urgent situations the system may contact a hospital and/or order an ambulance.

The use of unified messaging with a voice recognition facility allows for such flexible use of the communications network. A suitable voice recognition system is commercially available from Nuance Inc. of California USA.

The use of unified messaging permits the physician to program the system with a hierarchy of ways of contacting him. At the top of the hierarchy may be e-mail to his desk. At a lower end of the hierarchy there may be a mobile telephone and/or a pager and finally there may be a facility for leaving a notification at his desk if all other methods fail to reach him.

Reference is now made to Fig. 9b which shows a second embodiment of the present invention. In the embodiment of Fig. 9b Parts that are identical to those shown above are given the same reference numerals and are not referred to again except as necessary for an understanding of the present embodiment. Fig. 9b differs from Fig. 9a in that a server 2019, preferably associated with the network 2016,

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supports one or more users of the home monitoring system, who are able to communicate with it using any form of unified messaging, that is to say vocally, digitally via the typed word, digitally via data files, or in any other way. The server is able to process the data received, in the manner that will be described below, send responses to the user and pass it on to a physician or other care provider or to a staffed center.

Reference is now made to Fig. 10 which is a generalized block diagram showing in greater detail the system that has been described above in respect of Fig. 9. In Fig. 10, parts which are the same as those described in the previous figure are given the same reference numeral and are not described again except as necessary for an understanding of the present figure. The measuring device 2014 is preferably connected to a data processing device 2012. In accordance with a preferred embodiment of the invention, personal parameter measuring software 2020 is resident on at least one of the data processing devices 2012 and/or on at least one server 2032 for measuring at least one personal parameter of at least one patient, being a user of one of the general purpose computers. The personal parameters may be any suitable medical parameter, such as, for example, parameters relating to heart function, lung function, hearing, vision, alertness, physical appearance and perception as well as conventional medical indications such as weight, height, age, blood pressure, blood sugar level and other body fluid parameters, as well as various combinations of the foregoing.

Personal parameter measuring software preferably cooperates with measuring device 2034 which is preferably adapted to measure each type of personal parameter in association with a general purpose computer 2010. Various types of measuring devices 2034 may be provided to users of the system. For example, a stethoscope transducer and lung sounds interface may be provided for sensing lung sounds, electrocardiogram electrodes and an electrocardiogram interface may be provided for electrocardiogram measurements, and a hearing testing headset and headset calibrator may be provided for hearing testing.

It is appreciated that various calibration functionalities, which may be embodied in hardware, software or combinations thereof, may be provided as part of measuring device 2014 or for use therewith. The calibration functionalities may or may not involve communication with the server 2032 via the network 2016. A given

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calibration functionality may operate automatically without operator intervention. Alternatively, a calibration functionality may require operator activity.

It is further appreciated that at every appropriate stage of operation, suitable instruction may be provided to the user by the data processor 2012 of the user. This instruction may be presented to the user in textual, audio or multi-media form and may be unidirectional or interactive. Preferably, suitable instruction is provided prior to calibration of measuring device 2014, prior to establishment of a baseline and prior to each test.

The data processor 2012 is in turn connected to a messaging device 2028 which may be a modem or a fax or a telephone or a cellular phone or any other messaging device. The messaging device 2028 is operative to send data through a network to a unified messaging device 2030. The network may for example be the Internet or other wide area network or a LAN. In the case of a telephone, fax or cellphone, the network will be the public switched telephone network.

The unified messaging device 2030 may be connected to or may be part of a server 2032 on which are based data processing routines of the type to be described below for processing measurements made by the messaging device 2014. Alternatively some or all of the data processing could be performed at the processor 2012. The unified messaging device 2030 is operative to receive messages from any messaging device.

As an alternative, the patient may be given a measuring device 2034 which has a data readout. The user manually inserts the readout data, perhaps using a keyboard, into his messaging device 2036, which may be a computer or a telephone or any other suitable messaging device. In the case of a telephone the data could be spoken into the telephone provided that appropriate voice recognition software is available at the receiving end.

Thus an embodiment of the invention in which the user is required to use a telephone to contact the server 2019 may typically utilize voice recognition software at the server 2019. The user contacts the server which automatically greets the user and preferably asks for a user name or number. The name or number may be spoken in to the phone or keyed in using the keypad. Then the user may be asked to speak or key in the results of particular tests and finally the user may be given spoken instructions as to how to proceed. The server processes the data received as with

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other methods of data capture, as will be described below and the physician is contacted as necessary.

In accordance with a preferred embodiment of the present invention the medical condition sensing system of the present invention includes personal parameter reference generating software, preferably usable by the physician as will be described below. The personal parameter reference generating software may typically be resident on a general purpose computer to which the physician has access including the server 2032, for establishing a reference for the at least one personal parameter. In this preferred embodiment, personal parameter comparison software, resident on the data processor 2012 and/or on at least one server 2032, compares at least one currently measured personal parameter with a corresponding reference and provides a comparison output.

A comparison output may be provided to the user by the data processor 2012 together with an action recommendation. Alternatively or additionally, it may be provided to a controller computer 2016 for comparison with reference data stored on a central database 2034 in order to provide additional information and recommendations to the user.

A manned center may be associated with the server 2032 for providing a human interface and/or input as required. The manned center, which is preferably staffed by physicians or other health professionals, and in particular by the user's personal physician or health care professional, may be in direct telephone or possibly videophone contact with the user. Thus video cameras (not shown) are preferably provided both at the manned center 2036 and at various user locations.

In accordance with a preferred embodiment of the present invention, acceptable ranges of values for various medical parameters used in the present invention and different response regions within those ranges may be established by medical personnel in the manned center 2036 in accordance with the personal characteristics of each given patient, as will be described below. Such settings are preferably carried out by the patient's personal physician.

As necessary, the server 2032 is able to contact other messaging devices 2038 and 2040 which may be for example the physician or the hospital.

In accordance with one preferred embodiment of the present invention, communication with the manned center may be actuated automatically by the system, for example in response to a sensed personal parameter or to the comparison

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output being beyond a given threshold, for example being a red parameter as will be described below. Communication with the manned center may also be initiated by a user, at the user's initiative. Communication between the user and the manned center may be via the network 2016 including via conventional telephone or video-conference facilities.

Further in accordance with a preferred embodiment of the present invention, there is provided a recording and storage facility 2042 for off-line communication between the physician/care provider and the user, preferably associated with the server 32, for recording and storing sensed personal parameters.

There may also be provided for operation in the data processor 2012 or in the server 2032, software providing a comparison facility for comparing personal parameters and a result categorization facility for category regions to a comparison result in accordance with rules set by the physician on a per patient or per group of patient basis as will be described below and providing an indication of a selected category. The software may include signal processing functionality, where the measurement requires it.

Additionally in accordance with a preferred embodiment of the present invention, there is provided additional software which controls measurement of the personal parameters and which may communicate via the network 2016 with at least one remote computer. The measurement control software, which may reside both at data processor 2012 and at server 2032, preferably provides encryption encoding of information liable to be communicated over insecure parts of network 2016.

Preferably, there is associated with each data processor 2012, standard interface devices which may include at least one of a display, a printer and an audio input/output transducer, as well as a user graphics interface such as a mouse and an IP telephone. A conventional telephone is preferably available at each user location in addition to the messaging device 2028 which may be a modem.

In accordance with a preferred embodiment of the present invention communication between a data processor 2012 via the network 2016 with another data processor 12 or with a server 32 is encoded or encrypted using conventional technology suitable for this purpose.

In one embodiment, the server 2032 is provided with access to medical databases which provide reference material for presentation to the user as well as information which can be used by the server 2032 or by the physician to evaluate

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measured personal parameters and to determine suitable courses of treatment therefore and suitable parameter boundaries and rules, as will be explained below.

In accordance with a preferred embodiment of the present invention, the home observation system of the present invention includes:

a multiplicity of general purpose computers or other data processing devices disposed in user locations and being connected via a network such as a computer network to at least one server remote from at least one of the user locations;

personal parameter measuring software resident on at least one of the multiplicity of general purpose computers and at least one controller computer for measuring at least one personal parameter of at least one user; and

personal parameter analysis software resident on at least one of the multiplicity of general purpose computers and the at least one controller computer for analyzing at least one personal parameter of at least one user.

The distributed processing thus provided has a number of advantages, including reduced communication load and increased speed of response. Furthermore, such processing enables medical confidentiality to be readily maintained in communications over the computer network.

Preferably, at least one of the general purpose computers and the at least one controller computer serves as a backup for another one of the general purpose computer and the at least one controller computer.

This backup functionality preferably enables the system to overcome computer failures at either a general purpose computer at a user location or a controller computer, by transferring computing functionality to another computer connected thereto via the computer network. Should a network failure occur, but the general purpose computer at the user location is functioning, the user nevertheless can receive basic information as well as indications and recommendations as described hereinbelow from the general purpose computer. Additionally, as the system uses unified messaging, a bypass telephone connection may be employed to provide necessary communication with a user.

Reference is now made to Fig. 11, which is a schematic diagram showing a general principle behind a preferred embodiment of the present invention. Medical data 2050 which has been obtained from measurement device 2014 is input into a processor device 2052. The processor processes the data only in accordance with a

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series of boundary levels and combination rules that have been set specifically by the physician for a given patient or group of patients. The input data may contain the results of a plurality of measurements. Each separate result is preferably analyzed into results 2054. The results are a series of categories, for example red, amber and green, wherein red is a serious medical condition category indicating that immediate outside professional medical intervention is necessary in its own right, amber is a less serious category indicating, perhaps that action should be taken by the patient but outside professional medical intervention is not necessary unless the result is combined with results of other more serious indications.

It should be noted that more or less than three categories may be used as appropriate and that individual categories may be divided into subcategories. For example the red category may be divided into a low red category indicating making contact with a physician and a high red category indicating that an ambulance should be called urgently.

In general, the patient is given an indication of his current medical condition in the three color categories presentation with the associated recommendations or orders. The physician preferably receives red category results immediately and the remainder as trend or pattern data.

The measurement values are preferably associated with result categories fully in accordance with settings made by the physician for the individual patient or a group of patients as will be explained below.

Although Fig. 11 shows three categories of results, and as mentioned above, sub-categories are also possible and the skilled person will appreciate that new categories could be defined. The creation of new categories could be made as part of the system definition at programming or setup time or it could be offered to the physician to set up new categories on a per patient basis or a per group of patients basis.

Reference is now made to Fig. 12, which indicates a physician 2060 setting parameter boundaries for categorizing results of a particular measurement.

In Fig. 12 the physician 2060 makes use of a parameter value region selection and categorization tool for setting boundaries in a variation range of the parameter. The tool as shown is for categorizing a single parameter. The parameter may be measured by the patient, measured by a laboratory or, as will be described below, it may not be a measurement but rather a symptom.

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The tool enables the physician to define regions therebetween and to categorize the regions. The tool comprises the following:

1) A visual representation of the variation range as a linear continuum or bar 62.

2) A continuum divider for visually dividing the continuum at user selectable points therealong. The continuum divider preferably comprises a user-selectable number of sliders 2066 operable to be moved or dragged by a user to various points he has selected as boundaries between regions calling for different types of response. The number of sliders is selected by the user in accordance with the number of such regions he chooses to define, and

3) A category selector for associating any one of a group of predefined categories with any of the regions. The bar 2062 preferably displays each region using a color, typically red, amber or green, which has been pre-associated with the category.

The physician makes use of the bar 2062 which appears on his screen 2064 and which represents the dynamic range of the parameter being measured. The sliders 2066 appear on the sides of the bar 2062, which sliders may be moved using a mouse or by selecting the slider and then using arrow keys on the keyboard. Alternatively the sliders may be moved using any other form of user screen interaction equipment, for example using a light pen, touch screen or voice commands. The sliders are moved to define boundaries and then categories are preferably associated with the regions so formed. Colors such as the traffic light colors red, amber and green referred to above may have been pre-associated with the categories and thus the regions on the bar 2062 may be displayed using the relevant associated color as described above. Preferably the categories are associated with colors having meanings that the user is likely to associate with the category. For example, if using the traffic light colors then red should be associated with a category requiring urgent action, green with a category indicating no action required and amber with an intermediate category.

In a preferred embodiment, the colors are selectable by the physician. The physician may for example decide not to use the traffic light colors for a patient suffering from red-green color-blindness.

In another preferred embodiment the traffic light colors may be displayed as a traffic light icon 2078, enabling the color-blind patient to recognize the color

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from the position. In one embodiment, free color selection is available to the physician, with the option to choose the use of a traffic light icon in the case of choosing the traffic light colors.

As shown in the drawing, several regions may be given identical categories. In the example illustrated, red regions 2068 are shown at both the top and the bottom of the drawing. Amber regions 2070 are shown adjacent to the red regions 2068 and an inner green region 2072 lies between the two amber regions.

In a preferred embodiment, the bar 2062 is displayed in association with a graph 2076 which shows actual data points of said parameter, scaled to coincide with the scale of the bar 2062 itself. The data points preferably come from the patient himself and the measuring system. The graph may be useful in assisting the physician to define regions on the bar 2062.

In an embodiment in which the data comes from the patient himself, the graph is useful in allowing the physician to follow recent trends of the parameter *vis a vis* the patient and to alter the regions in accordance with the monitored trends.

Alternatively or additionally to displaying graphical data, it is possible to display a numerical scale along the bar 2062, again to assist the physician in selecting the regions.

It will be appreciated that certain rules may be applied to region formation, for example that red and green regions cannot be adjacent each other but must be separated by an amber region of finite thickness. Again, the rules may be applied by the programmer as global rules or they may be applied by the physician when defining new categories or they may be applied by the physician on a case by case basis. In an alternative embodiment, rules need not be applied at all.

Each region may have labels 2074 attached thereto. The attachment of labels is preferably carried out by the physician on a patient-by-patient basis. Labels 2074 may be qualitative labels of the measurement such as high, normal and low, and may be accompanied by recommended actions such as "seek physician attention" or "no reaction".

Reference is now made to Fig. 13a, which is a simplified diagram showing how the features of Fig. 12 may be applied to the measurement of systolic blood pressure. Boundaries are, for example, set at 90, 100, 140 and 190 mm of mercury. A green region is recorded between 100 and 140 mm, amber regions between 90 and 100mm and between 140 and 190, and red regions below 90 and above 190mm of

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mercury. A series of recommended actions are shown opposite each region which the patient is asked to follow. Generally in green regions no specific action is recommended other than perhaps to repeat previously defined orders/ recommendations by the physician or care provider. In an amber region patient administered treatment is recommended and in a red region physician intervention is called for. It will be noticed that separate regions of the same color are autonomous and need not have the same recommendations.

In the embodiment illustrated, boundary values between the regions are displayed.

A further parameter that the physician may introduce is a maximum change in a parameter. A particular level of a parameter may not of itself give cause for concern but if that level is the result of a very rapid change compared with previous measurements then this may lead the physician to investigate the matter further. The physician is therefore able to introduce a maximum percentage change per test parameter or an absolute change per test parameter. The maximum change may then be given a color category and associated with a recommendation as with the other readings and be treated in exactly the same way.

Reference is now made to Fig. 13b which is identical to Fig. 13a except that the maximum change between tests is 24% instead of 20%. The higher tolerance may be set by the physician where he is more confident in the patient, perhaps in the case of a younger patient. Either way, this illustrates the point that selection of the parameters is made by the physician on a per patient basis.

Reference is now made to Fig. 14a, which is identical to Fig. 13a except that the system has been programmed to measure diastolic blood pressure. The absolute values chosen for the region boundaries are thus correspondingly lower by about 30mm of mercury but the regions and the associated recommendations are the same. The regions and associated recommendations or actions of course need not be the same, and are preferably set individually for the patient. The maximum allowable change between readings is also unchanged in this example.

Reference is now made to Fig. 14b which is identical to Fig. 14a except that the maximum change between tests is 19% instead of 20%. The lower tolerance may be set by the physician where he is less confident in the patient, perhaps in the case of an older patient. Either way, this illustrates the point that selection of the parameters is made by the physician on a per patient basis.

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Reference is now made to Fig. 15a, which shows how a set of readings may be combined to produce new regions using a simple set of combinatorial rules which are set, preferably on a patient by patient basis, by a physician. In Fig. 15 the two separate systolic and diastolic blood-pressure measurements are each assigned a category as before. Three possible results 2080, 2082 and 2084 are shown. In the first two sets of results, 2080 and 2082, both the systolic and diastolic blood pressures are shown in the same amber region, that is to say both are in the amber high region 2080, or both are in the amber low region 2082. The physician defines such combinations as producing a combined result which is either amber high 2086 or amber low 2088 as appropriate.

If, as in result set 2084, one is in the amber high region and the other is in the amber low region, indicating a very large pressure difference, a combined outcome 2090 of red is given, even though neither of the individual readings suggests red.

The maximum change between tests is also taken into account as result set 2092. If the maximum change between tests is lower than the threshold value set by the physician then the result is green. If the maximum change is larger than the threshold then the result is red.

Reference is now made to Fig. 15b, which shows the same information as that in Fig. 15a except that the information is summarized more concisely.

Reference is now made to Fig. 16a, which shows how the same set of measurements may be combined together differently to produce different outcomes, perhaps for a younger patient where the physician is less concerned about complications. In Fig. 16 the two separate systolic and diastolic blood-pressure measurements are each assigned a category as before. Three possible results 2100, 2102 and 2104 are shown. In the first two sets of results, 2100 and 2102, both the systolic and diastolic blood pressures are shown in the same amber region, that is to say both are in the amber high 2100, or both are in the amber low, 2102. The physician defines such combinations as producing a combined result 2106 of green.

If, as in result set 2104, one is in the amber high region and the other is in the amber low region, indicating a very large pressure difference, a combined outcome 2110 of red is given as before. However, the physician or care provider may override the red outcome with an amber outcome which he may associate with different orders.

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Reference is now made to Fig. 16b, which shows that if two green results are produced, (top row) then the output is green. If on the other hand any of the outputs are red (bottom row) then the overall result is necessarily forced to red.

Reference is now made to Fig. 16c, which is a simplified diagram showing the information of Figs. 16a and 16b in more compact form.

Reference is now made to Figs. 17a to 17d which are simplified diagrams showing different outcomes of making a series of measurements of weight, blood pressure, heart rate and blood potassium level. The blood pressure may be the individual systolic or diastolic blood pressures or the result of combining the two as described in Figs. 14 and 15.

As described above with blood pressure, critical boundary levels for all of the above measurements are preferably set by the physician on a patient by patient basis. For example acceptable and non-acceptable body weight is generally perceived as a function of height.

In Fig. 17a all of the tests, that is, for weight, blood pressure, heart rate and blood potassium level, give results which are categorized as green. The patient is simply asked to repeat the tests at a routine interval.

In Fig. 17b, the heart rate and potassium tests reveal normal results which are categorized as green. The weight and blood pressure give amber results which each generate individual order(s) or recommendation(s) but the physician has not programmed any special recommendation for this particular combination of results. Thus the patient is simply presented with the two amber recommendations for weight and blood pressure.

Fig. 17c shows all three of the tests for weight, blood pressure and heart rate returning amber. The potassium test returns green. Such a combination of three amber results has here been set to return an overall red and the patient is advised to contact his physician.

Fig. 17d shows that the weight test has produced a result of red. The blood pressure test and the potassium tests have returned green and the heart rate test has returned amber. In this case, the overall result is red and the patient is once again asked to contact his physician.

Reference is now made to Fig. 18, which is a simplified functional block diagram illustration of the general functionality of a data processing device 2012

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such as a general purpose computer and of an optional personal parameter transfer interface, both forming part of the system of Fig. 10.

In the example shown in Fig. 18, the measuring device, or personal parameter measuring equipment, is directly connected to a data processing device which carries out local processing of the data. As described above, it is also possible for data processing to be carried out remotely, via the network 2016.

It is appreciated that the personal parameter transfer interface typically forms part of personal parameter measuring equipment 2022 (Fig. 9) and may have different configurations depending on the personal parameter which is sought to be measured and, in certain cases, may be obviated. An example where the interface may be obviated is the hearing testing equipment which may employ a headset. A headset may be connected directly to a general purpose computer incorporating a sound card without requiring any special interface.

As seen in Fig. 18, personal parameter measurement equipment 2014, such as a stethoscope transducer, electrocardiogram electrodes and headset, is coupled to optional personal parameter interface circuitry, designated generally by reference numeral 2103. Circuitry 2103 typically includes one or more of the following components: a filter 2107, an amplifier 2109, a memory 2108, a microprocessor 2110, a power supply 2112, a wireless communications interface 2114 and a wired communication interface 2116. Where a memory 2108 or a wireless interface 2114 is provided, the interface circuitry 2103 may be portable and thus particularly useful for emergency applications.

Typically the personal parameter interface circuitry 2103 is coupled to a suitable port of a data processing device 2012 (Fig. 9), such as a serial port, a sound or game port or a universal port and permits outputs to be supplied to the data processing device 2012 for processing thereat.

Recording and storage facility 2040 (Fig. 9) may, as an alternative to being associated with the server 2032, be provided at data processing device 2012 for recording and storing parameters received by the data processing device 2012 during at least one test. Preferably, the recording and storage facility 2040 comprises signal receipt and storage facility 2120, a signal processing facility 2122, a signal analysis facility 2122 and an information storage facility 2124. Optionally, any one or more of the foregoing functionalities may be obviated.

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Software which is preferably resident in data processing device 2012, provides appropriate signal processing and comparison of parameters received by the data processing device 2012 and may apply a series of thresholds to a comparison result, as described above, in order to apply categories thereto. The software typically provides, via data processing device 2012, an indication of the applied categories along with a suitable description of the situation which may be accompanied by recommendations for action.

The software typically comprises comparison functionality 2130 which may receive information representing stored region boundaries and/or a test and which may provide an output to a category selection functionality 2131. A second category selection functionality 2132 comprises the rules set by the physician for categorizing combined outcomes, as described above in respect of Figs. 14 to 17d. A condition description functionality 2134 preferably receives information relating to at least one of the stored baseline and the test and may also receive outputs of the comparison and category application functionalities 2130 to 2132. The condition description functionality preferably provides outputs to one or more output devices such as a user screen as well as optionally via network 2014 to controller computer 2032 and/or to the associated manned center referred to above.

The condition description functionality may also provide an output to recommendation functionality 2136, which preferably also receives inputs from comparison functionality 2130 and category application functionality 2132.

In accordance with a preferred embodiment of the present invention the general purpose computer 2010 may communicate with a remote computer, such as a controller computer 2016 (Fig. 9), for obtaining additional reference data and possibly carrying out a comparison between the test data and reference data, thereby to provide further information to the user. Such further information may include a more detailed or precise description of the condition indicated by the test results which may be accompanied by a more detailed or precise recommendation for action. Information received via the network may be employed by the recommendation functionality 2136 as well as by the condition description functionality 2134.

Communication with a remote computer, such as a server 2032 may be initiated automatically by the data processing device 2012 via the network 2016, for

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example in response to a red categorization. Communication via the network 2016 with the controller computer may also be initiated by a user, at the user's initiative.

Condition description functionality 2134 and recommendation/ order functionality 136 preferably operate in association with a database 2140 which stores acceptable ranges of outputs of comparison functionality 2130, normalized for age, weight, height, sex and possibly other characteristics. It may also contain standard personal parameter data, for example normal values of personal parameters for a given user or users. The database information is preferably not directly employed in making decisions, as these should be based only on rules and parameter boundaries entered by the physician on a patient by patient basis.

It is appreciated that any one or more of the functionalities and databases described hereinabove in the context of software 2042 may be obviated in a given application.

Communication with a remote computer, such as server 2032 (Fig. 10) via the network 2016 may be actuated automatically in response to the output of comparison functionality 2130, category application functionality 2131, 2132, condition description functionality 2134 or recommendation functionality 2136. Thus, when a sensed personal parameter or combination causes a category output of red, which may indicate either an emergency situation or a situation requiring physician intervention, communication is established immediately between the user's data processing device 2012 and the server 2032 via the network 2016.

Communication between the user and the manned center may be via the network 2016 and/or via conventional telephone or video-conference facilities.

Reference is now made to Fig. 19, which is a simplified schematic diagram showing a symptom notification feature which may be incorporated into a home observation system of the present invention. A patient who feels a particular symptom 2200, is able to select the symptom 2200 and categorize the symptom using various levels of severity 2202, for example, normal, mild, moderate, severe and very severe.

In one embodiment the available symptoms are selected by the physician on a per patient basis, so that the patient is restricted to the selection of features that are relevant to his course of treatment. In accordance with another embodiment, the patient may be given a comprehensive list of symptoms to choose from.

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The patient typically responds in terms of the selection of categories which are broadly the same for all patients. However, the physician may tailor response levels to his knowledge of the patient. For example a patient with a high tolerance of pain and low propensity to hypochondria, may be assigned higher response levels to lower categories of symptom than other patients.

Reference is now made to Fig. 20 which is a simplified schematic diagram showing in more detail the symptom notification feature of Fig. 19. In Fig. 20 a series of symptoms 2206.1..2206.n are selected by the physician, preferably as being relevant to the treatment or condition of the patient. Then a series of response categories 2202 are selected as before and each response category is associated with a qualitative statement 2208.1..2208.5 about the symptom in the language of the patient, which the patient is able to understand clearly and choose from. Typical statements may include "I feel well", "I feel slight discomfort", I feel moderate discomfort and weakness", "I feel weak and bad" and "I feel very bad". The exact content of the statements is preferably selected by the physician on a per symptom and a per patient basis.

Reference is now made to Fig. 21, which is a simplified schematic drawing showing how the symptom notification system may be integrated into a home observation system of an embodiment of the present invention. In the system of Fig. 21, the five categories 2202 into which the symptoms were categorized in previous figures are mapped onto the three traffic light colors. The mapping is preferably done by the physician on a per patient and a per symptom basis. In the illustrated example, the normal level is mapped onto green and the very severe level is mapped onto red with the remaining intermediate categories being mapped onto amber. The skilled person will be aware that other forms of mapping or coloring are possible. As described above, the green category indicates that all is well and the red category indicates a situation to be reported immediately to the physician. The amber categories typically lead to advice being given to the patient and only lead to a notification being made to the physician if they are combined with other amber signals which as a combination cause a red categorization to arise.

Reference is now made to Fig. 22, which is a schematic diagram showing how an embodiment of the home observation system communicates with the patient and with the physician, particularly in the case of the symptom notification embodiment. In the system notification embodiment, the patient receives

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recommendations associated with any one of the five categories 2202 with which the symptom has been associated. The fact that the categories were later mapped onto three system categories has no bearing on the first level recommendations made in response to the symptom notification. The three system categories, however, do effect the way in which the symptom notification is combined with other effects to produce secondary categories.

On the other hand the physician receives an immediate alert if any of the recorded symptoms or measurement lead to a red category, either as a primary or a deeper category. The physician also preferably receives regular reports showing trends in the data collected.

Reference is now made to Fig. 23, which is a schematic diagram showing how a physician may be alerted in the event of a red category or may receive a routine report in the event that there are no red categorizations. In Fig. 23 an indicator bar 2210, similar to the parameter value region selection and categorization tool of Fig. 12, appears at the left of the screen. A graph area 2212 appears to the right of the bar 2210, on which are plotted various data points obtained from the home observation system and from these, the physician is able to identify significant trends. A numerical value region 2214 shows various numerical data such as a present value of the parameter, a difference between the present parameter value and a preselected previous value, and a value indicating a trend or pattern. An area 2216 to the right of the screen shows patient particulars.

Reference is now made to Fig. 24, which is a generalized schematic diagram showing how patient notification may be carried out in accordance with a preferred embodiment of the present invention. As mentioned above, the content of any particular patient notification depends on the categories 2202 associated with each symptom or measurement. However the form of notification and content of the notification preferably fit into the three system categories, such that notifications in the red category are of the nature of "contact your physician" or head for the hospital emergency room" and the like. The amber category contains directions for action to be carried out by the patient and the green category generally contains an indication that routine monitoring is to continue.

Reference is now made to Fig. 25, which is a simplified layer chart indicating different layers of customization of an initial knowledge base on which embodiments of the present invention may be based. In Fig. 25, an initial level 2220

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represents a general system containing the three system categories and the ability to incorporate a large range of parameters to work alone or in combination to produce primary and deeper categorization results. The first level represents an initial starter set of problems to be tracked and recommendations/ orders to be associated with different status results and output categories. Typically the starter set knowledge base is predefined at the level of the healthcare organization to form a series of general profiles or templates that allow the monitoring regime to correspond to routine procedures or to after care facilities.

A second level 2222 represents a second level of customization that may be provided globally by a care provider such as a physician or a hospital. The physician or the health care provider may use the definitions, profiles or templates defined in the first level or may prepare his own definitions from scratch. The second level allows the physician, hospital etc. to provide a set of more detailed definitions, profiles or templates for specific problems or complaints, that may serve with minimal modification for large numbers of patients.

A third layer of customization 2224, at the patient level is preferably carried out by the physician per the specific patient where required. This capability is provided in order to enable the physician to modify the system behavior per each patient, in the context of a specific health care problem being monitored and thus overriding or adding to the general definitions provided in levels 1 and /or 2 as deemed most suitable for each patient.

The physician preferably customizes the system for each one of the different conditions for which he is likely to require monitoring, for example hypertension 2224A, CHF 2224B, renal failure 2224C, malignancy follow up 2224D, asthma 2224E and liver disease 2224F. The physician is also able to program a generic type here labeled "other" 2224G which may be used for less routine cases. The system customized for each condition preferably contains the parameters to be monitored, general categorization levels, connections, and significant symptoms such as signs of deterioration or of reaction to the principle drug used in treatment. The system may then later be configured for the individual patient, with precise levels being set for the categorization regions, precise combinations to reach a given secondary results and the like.

Reference is now made to Fig. 26, which shows a series of medical parameters 2230 which may be combined in various ways to provide suitable

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monitoring systems. In the present case, the physician selects blood pressure and copies this to table 2232. A form 2234 allows him to enter patient record information, either manually or from an associated patient database.

Blood pressure measurement is not a single parameter measurement but rather is a complex of two measurements, diastolic and systolic blood pressure. Thus the physician must set primary and secondary categories for the two measurements in combination. Thus, the physician is invited to set regions of interest in the two parameters of systolic and diastolic blood pressure measurements as discussed earlier in respect of Figs 13a, to 14b, and to set relationships between them to establish secondary and consolidated results, as in Figs. 15a to 16b.

Reference is now made to Fig. 27, which is a schematic diagram identical to that of Fig. 26 except that the further parameters of weight, heart rate and urea level have been added to the parameters to be monitored 2232. These parameters are further parameters that it is desirable to measure in the case of congestive heart failure. The further parameters added in Fig. 27 are parameters that, in contrast to blood pressure, generally involve a single measurement.

Reference is now made to Figs. 28a to 28d which illustrate four rules that can be set for producing secondary categorizations of the results of the four parameters weight, blood pressure, heart rate and urea level. As will be recalled, the blood pressure result is itself a secondary categorization.

Each of the four parameters produces results in one of three system categories, red, amber and green. The three system categories give rise to five actual categories as follows: red high, amber high, green, amber low and red low.

In Fig. 28a, weight gives rise to a green result, blood pressure to an amber high result,, heart rate to an amber low result, and urea level to a red result. An overall consolidating result of red is produced by using a rule that states that the resultant category is red if any of the parameters gives red.

In Fig. 28b, weight gives rise to a green result, blood pressure to a green result, heart rate to a green result, and urea level to a green result. An overall consolidating result of green is produced by using a rule that states that the resultant category is green if all of the parameters are green.

In Fig. 28c, weight gives rise to a green result, blood pressure to an amber high result, heart rate to an amber high result, and the urea level to an amber low

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result. An overall consolidating result of red is produced by using a rule that states that the resultant category is red if three or more of the parameters give amber.

In Fig. 28d, weight gives rise to an amber low result, blood pressure to a green result, heart rate to a green result, and the urea level to a green result. An overall consolidating result of amber is produced and the patient is given instructions that have been associated with the primary amber.

The use of the above rules saves on programming individual combinations. As will be appreciated, when using four or more parameters the individual numbers of combinations can be quite large. However, using rules of this type may mask the behavior of certain parameters by treating them in the same way. Thus, as a further variation, it is possible to sign a parameter, as will be explained below.

Reference is now made to Figs. 29a to 29d which are simplified schematic diagrams of the way in which the same set of rules may be applied to a set of parameters one of which is signed.

Fig. 29a shows the same set of parameters given in Fig. 28a except that the urea level parameter is signed. In Figs. 20a to 20d two amber categories led to individual instructions for each amber without giving rise to any combined new category. As was shown in Fig. 15, an amber high category may be set to combine with an amber low category to produce a red. The use of this rule therefore depends on the polarity of the parameter. The polarity of the urea level parameter is important because an amber high represents a situation in which there is a high concentration of urea in the blood due to low levels of fluid in the bloodstream. This could be because fluid aggregates in the lungs or in the kidneys. On the other hand a low concentration of urea in the kidneys represents a high level of fluid in the blood. This could indicate renal failure. Thus the two amber signs mean very different things, need to be treated in different ways and need to be combined in different ways with the other symptoms.

In Fig. 29a, weight is shown as a low amber result, blood pressure as a green result, heart rate as a green result, and urea level as a low amber result. The two amber results, being both low ambers, do not trigger a red result,, and the final consolidated output is simply the two amber recommendations.

In Fig. 29b, weight is shown as a low amber result, blood pressure as a green result, heart rate as a low amber result, and urea level as a green result. The

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two amber results, being both low ambers, would not normally cause a red, however, because urea level is signed (i.e. polarized), it behaves as a high amber result, and triggers the rule that says that a high amber plus a low amber gives a consolidated result of red.

In Fig. 29c, weight is shown as a green result, blood pressure as a high amber result, heart rate as a low amber result, and urea level as a green result. The two amber results, one being a high amber and one being a low amber, trigger the rule that says that a high amber plus a low amber gives a consolidated result of red.

In Fig. 29d, weight is shown as a low amber result, blood pressure as a green result, heart rate as a low amber result, and urea level as a green result. The two amber results, both being low, do not trigger a red result, and the consolidated output is amber with recommendations for each of the individual ambers.

Reference is now made to Fig. 30 which is a generalized diagram showing an input form for programming a home monitoring system according to embodiments of the present invention. In Fig. 30, a full set of features that a physician may select for monitoring a patient suffering from congestive heart failure from a complete list of relevant parameters. Such selected parameters here include blood pressure, weight, heart rate, urea level, potassium level and PT.

In addition to studying congestive heart failure as described above, embodiments of the present invention are useful for monitoring patients suffering from any condition or illness or undergoing a course of treatment wherein continuous monitoring is needed. For example, it is also possible to monitor a patient for asthma. Relevant parameters for monitoring an asthma patient are heart rate, breathing rate and peak airflow.

A patient suffering from renal failure may also be monitored by the equipment of embodiments of the present invention. Typical parameters for selecting in the event of renal failure may be weight, urea level, potassium level and creatinine level.

The equipment of embodiments of the present invention may be used to monitor chemotherapy patients. A typical symptom that may be included in the case of a chemotherapy patient would be a burning sensation in the legs. Such a symptom is indicative to the physician that the treatment should be modified.

Reference is now made to Fig. 31, which is a simplified diagram of a system for data capture over a telephone line which may be used in embodiments of

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the present invention. In Fig. 31, a telephone 2240 is connected via the public switched telephone network 2242 to a voicemail box 2244. The voicemail box 2244 is connected to sound processing equipment 2246 which is operable to recognize voice and tone input and convert it into textual form, and is able to output sound towards the telephone line, perhaps by using an electronic voice as a text to sound converter. A data capture unit 2248 takes textual data from the sound processing unit 2246 and places it on a form 2250. The sound processing device is operable to take labels from the form and read them out over the telephone line to form the questions which the user is required to answer. When the form 2250 is completed, following a question and answer session between the user and the system, the form is submitted to a server 252 for processing. An indication of his condition, and recommendations or instructions may then be read out automatically to the user.

In a variation of the embodiment of Fig. 31, in place of a textual form, data is entered in a format suitable for processing directly by the server.

Embodiments of the present invention thus provide a system in which parametric data is obtained from a patient and is processed according to a set of rules or filters which essentially quantize the data into primary categories.

The data that may be processed by the system includes primary data such as parametric data, and symptomatic data, and secondary data such as levels of change in the primary data.

Labels are associated with the categories and combinatorial rules allow for the selection of secondary categories. The secondary categories, which may occur at one or more levels, may also be associated with labels.

The filtering into primary and secondary categories may occur at the patient end, at a server or with a physician. The rules are preferably set on a per patient basis by the physician although the physician may use generalized templates from which to build an individual patient profile.

The physician is preferably able to obtain data about the patient in graphical format, conveniently showing trends and patterns. An upward trend in the data or a pattern showing large swings between high and low values may be a cause for concern even though the values themselves do not cross any preset or obvious danger thresholds.

The system allows the physician to modify the settings, on a per patient basis, in the light of his experience, research results or other information.

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The system may utilize unified messaging for alerting the physician to dangerous or red states of the patient.

It will be appreciated that although the present invention has been illustrated in the context of medical decision-making it is applicable in all cases in which trustworthy decisions are needed without the continuous presence of a professional.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the appended claims and includes both combinations and subcombinations of the various features described hereinabove as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description.

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Claims

1. A medical condition sensing system comprising:

a multiplicity of general purpose computers disposed in user locations and being connected via a computer network to at least one controller computer remote from at least one of said user locations;

personal parameter measuring software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for measuring at least one personal parameter of at least one user;

personal parameter reference generating software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for establishing a reference for said at least one personal parameter; and

personal parameter comparison software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for comparing at least one currently measured personal parameter with a corresponding reference and providing a comparison output.

2. A medical condition sensing system according to claim 1 and also comprising alert indication software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for providing a generally real time alert indication to said user based at least partially on said comparison output.

3. A medical condition sensing system according to claim 2 and wherein said alert indication software is resident on said multiplicity of general purpose computers.

4. A medical condition sensing system according to claim 1 and wherein said reference is a personal parameter baseline constructed from pre-real time measurements of said personal parameter.

5. A medical condition sensing system according to claim 1 and wherein said reference is a calibration reference employing a measurement of a personal parameter based on a calibration input.

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6. A medical condition sensing system according to claim 1 and wherein said reference is a calibration reference based on a calibration input.

7. A medical condition sensing system according to claim 1 and wherein said reference is a calibration reference based on a calibration input supplied from another computer via said computer network.

8. A medical condition sensing system according to claim 1 and wherein said reference is a calibration reference employing a measurement of a personal parameter based on a calibration input supplied from another computer via said computer network.

9. A medical condition sensing system according to claim 8 and wherein said personal parameter comparison software is operative to compare at least one currently measured personal parameter with said calibration reference.

10. A medical condition sensing system according to claim 1 and also comprising notification software resident on at least one of said multiplicity of general purpose computers and said at least one controller for transmitting a notification from one of said at multiplicity of general purpose computers to at least one other computer based on said comparison output.

11. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a heart function parameter.

12. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a blood parameter.

13. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a electrocardiogram parameter.

14. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a hearing function parameter.

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15. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a skin appearance parameter.

16. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a tissue appearance parameter.

17. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises an optically sensible parameter.

18. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises an electrically sensible parameter.

19. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises an thermally sensible parameter.

20. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises an audibly sensible parameter.

21. A medical condition sensing system according to claim 1 and wherein said personal parameter comprises a chemically sensible parameter.

22. A medical condition sensing system according to claim 1 and wherein said personal parameter comparison software is operative to compare optical images of at least one body region.

23. A medical condition sensing system according to claim 1 and wherein said personal parameter measuring software is operative to measure at least one personal parameter of at least one user in response to an input supplied to the user.

24. A medical condition sensing system according to claim 23 and wherein said personal parameter measuring software includes feedback software for calibrating the input supplied to the user.

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25. A medical condition sensing system according to claim 23 and also comprising feedback circuitry for calibrating the input supplied to the user.

26. A medical condition sensing system according to claim 24 and wherein said feedback software is operative to communicate between a general purpose computer and said controller computer over said computer network.

27. A medical condition sensing system according to claim 25 and wherein said feedback circuitry is operative to communicate between a general purpose computer and said controller computer over said computer network.

28. A medical condition sensing system according to claim 1 and wherein said personal parameter measuring software includes feedback software for calibrating a measured personal parameter of a user.

29. A medical condition sensing system according to claim 1 and also comprising feedback circuitry for calibrating a measured personal parameter of a user.

30. A medical condition sensing system according to claim 28 and wherein said feedback software is operative to communicate between a general purpose computer and said controller computer over said computer network.

31. A medical condition sensing system according to claim 29 and wherein said feedback circuitry is operative to communicate between a general purpose computer and said controller computer over said computer network.

32. A medical condition sensing system according to claim 1 and also comprising software utilizing the output of at least one of said personal parameter measuring software, said personal parameter reference generating software, and said personal parameter comparison software for providing at least one of recommendations and indications to a user.

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33. A medical condition sensing system according to claim 1 and also comprising a manned center accessible at least via said computer network for receiving at least some of said output of at least one of said personal parameter measuring software, said personal parameter reference generating software said personal parameter comparison software and at least one of recommendations and indications to a user and providing health professional interaction with the user.

34. A medical condition sensing system according to claim 32 and also comprising a manned center accessible at least via said computer network for receiving at least some of said output of at least one of said personal parameter measuring software, said personal parameter reference generating software said personal parameter comparison software and at least one of recommendations and indications to a user and providing health professional interaction with the user.

35. A medical condition sensing system according to claim 33 and wherein at least one of said recommendations and indications as well as the criteria therefor is determinable by a user's health professional by transmitting instructions to at least one of said controller computer and said general purpose computer via said computer network.

36. A medical condition sensing system according to claim 34 and wherein at least one of said recommendations and indications as well as the criteria therefor is determinable by a user's health professional by transmitting instructions to at least one of said controller computer and said general purpose computer via said computer network.

37. A medical condition sensing system according to claim 33 and wherein said manned center employs a personal physician of the user and communicates with him via through at least one of telephone and data links via at least one of wired and wireless communication media.

38. A medical condition sensing system according to claim 1 and also comprising personal parameter analysis software resident on at least one of said

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multiplicity of general purpose computers and said at least one controller computer for analyzing said at least one personal parameter of at least one user.

39. A medical condition sensing system according to claim 38 and wherein analysis of at least one personal parameter of at least one user takes place partially at a general purpose computer at at least one user location and partially at said at least one controller computer.

40. A medical condition sensing system according to claim 38 and wherein analysis of at least one personal parameter of at least one user at a general purpose computer at at least one user location provides an analysis output which determines whether further analysis of said at least one personal parameter is carried out at said at least one controller computer.

41. A medical condition sensing system according to claim 38 and wherein at least one of said general purpose computer and said at least one controller computer serves as a backup for another one of said general purpose computer and said at least one controller computer.

42. Apparatus for collecting medical data comprising:

a user station connected to at least one computer remote from said user station via a computer network;

a user interface connected to said user station; and

a calibration system operative to calibrate said user interface which employs communication via said at least one computer network.

43. Apparatus for collecting medical data according to claim 42 and wherein said calibration system operates automatically without operator intervention.

44. Apparatus for collecting medical data according to claim 42 and also comprising personal parameter analysis software resident on at least one of said user station and said at least one computer for analyzing said at least one personal parameter of at least one user.

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45. Apparatus for collecting medical data according to claim 44 and wherein analysis of at least one personal parameter of at least one user takes place partially at said user station and partially at said at least one computer.

46. Apparatus for collecting medical data according to claim 44 and wherein analysis of at least one personal parameter of at least one user provides an analysis output which determines whether further analysis of said at least one personal parameter is carried out at said at least one computer.

47. Apparatus for collecting medical data according to claim 44 and wherein at least one of said user station and said at least one computer serves as a backup for another one of said user station and said at least one computer.

48. Apparatus for collecting medical data comprising:

a general purpose computer;

a user interface connected to said computer;

a recording and storage facility for recording and storing at least one baseline result received by said user station using said user interface from at least a first test taken at least a first time; and

a comparison facility for receiving at least one subsequent result received by said user station using said user interface from at least a second test, similar to said first test, taken at at least a second time, later than said first time, comparing said at least second test with said at least first test, applying a threshold to a comparison result and providing an indication in response to exceedance of said threshold.

49. A user interface assembly suitable for use in apparatus for collecting medical data including a user station connected to at least one computer remote from said user station via a computer network, said user interface assembly comprising:

a user interface coupled to said user station for use in collecting medical data from a subject;

software usable by said user station to control the operation of said user interface and to communicate via said computer network with said at least one computer remote from said user station.

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50. A user interface assembly according to claim 49 and wherein said software is useful at least to communicate data required for calibration of at least one of said user interface and said user station.

51. A user interface assembly suitable for use in apparatus for collecting medical data including a general purpose computer, the user interface assembly comprising:

a user interface coupled to said user station for use in collecting medical data from a subject;

software usable by said general purpose computer and providing at least the following functionality:

a recording and storage functionality for recording and storing at least one baseline result received by said general purpose computer via said user interface from at least a first test taken at at least a first time; and

a comparison facility for receiving at least one subsequent result received by said general purpose computer using said user interface from at least a second test, similar to said first test, taken at at least a second time, later than said first time, comparing said at least second test with said at least first test, applying a threshold to a comparison result and providing an indication in response to exceedance of said threshold.

52. A medical condition sensing system comprising:

a multiplicity of general purpose computers disposed in user locations and being connected via a computer network to at least one controller computer remote from at least one of said user locations;

personal parameter measuring software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for measuring at least one personal parameter of at least one user;

personal parameter analysis software resident on at least one of said multiplicity of general purpose computers and said at least one controller computer for analyzing said at least one personal parameter of at least one user.

53. A medical condition sensing system according to claim 52 and wherein analysis of at least one personal parameter of at least one user takes place

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partially at a general purpose computer at at least one user location and partially at said at least one controller computer.

54. A medical condition sensing system according to claim 52 and wherein analysis of at least one personal parameter of at least one user at a general purpose computer at at least one user location provides an analysis output which determines whether further analysis of said at least one personal parameter is carried out at said at least one controller computer.

55. A medical condition sensing system according to claim 52 and wherein at least one of said general purpose computer and said at least one controller computer serves as a backup for another one of said general purpose computer and said at least one controller computer.

56. A parameter evaluation system comprising a boundary input device for setting boundaries in a variation range of one or more parameters, thereby to define regions within said variation range, a label input device for associating labels with said regions, a rule input device for setting rules to associate at least one of a plurality of output recommendations with each of said regions and with combinations thereof and an output device to present a user with an output recommendation associated with a region or combination thereof corresponding to at least one measured parameter input to said system.

57. A system according to claim 56, wherein said boundary input device comprises a bar having a length representative of a variation range of a respective parameter.

58. A system according to claim 57, wherein said boundary input device further comprises slidable boundary points for sliding along said length and wherein said regions are defined between said slidable boundary points.

59. A system according to claim 58 wherein said label input device is operable to associate one of a plurality of labeling colors with at least one of said regions.

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60. A system according to claim 58 wherein said label input device is operable to associate a labeling color with a combination of said regions.

61. A system according to claim 56 in which said label input device is operable to label at least one of said regions with one of a group of categories.

62. A system according to claim 61 in which at least one of said categories is associated with a procedure for making automatic contact with a remote site.

63. A system according to claim 62 wherein said procedure utilizes any one of a group comprising internet messaging, telephone messaging, paging and fax messaging to reach said remote site.

64. A system according to claim 56, further comprising an interface for connecting a measuring device thereto.

65. A system according to claim 64 further comprising a measuring device attached to said interface for providing to said system a measured parameter.

66. A system according to claim 56, wherein said parameter is a body medical parameter.

67. A system according to claim 56, further comprising a list of at least one symptom, selectable by a user and classifiable by said user according to degree of severity, and wherein said rule input device is usable to set rules which incorporate said rule input device with said parameters to produce said output.

68. A system according to claim 56 wherein at least one parameter is signable to influence an output.

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69. A parameter value region selection and categorization input device for setting boundaries in a variation range of a substantially continuously variable parameter, defining regions therebetween and categorizing said regions, said device comprising:

a visual representation of said variation range as a linear continuum,

a continuum divider for visually dividing said continuum at user selectable points therealong, said points corresponding to values of said parameter, thereby to define regions therebetween and

a category selector for associating one of a group of predefined categories with at least one thus-defined region.

70. A device according to claim 69, wherein said continuum divider comprises a user-selectable number of sliders operable to be moved by a user to said user-selectable points.

71. A device according to claim 69, wherein each one of said predefined categories has a color associated therewith and wherein said device is operable to display each-thus defined region on said continuum using said color.

72. A device according to claim 69, further comprising an overlay unit for displaying said continuum in association with data connected with said parameter, thereby to assist in selection of said points.

73. A device according to claim 72, wherein said overlay unit is a graphical overlay unit operable to display said continuum in association with data connected with said parameter and graphically arranged and scaled according to said continuum.

74. A parameter value region selection and categorization input device for setting boundaries in a variation range of a substantially continuously variable parameter, defining regions therebetween and categorizing said regions, said device comprising:

a visual representation of said variation range as a linear continuum,

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a continuum divider for visually dividing said continuum at user selectable points therealong, said points corresponding to values of said parameter, thereby to define regions therebetween and

a category definer for defining categories for association with said regions.

75. A device according to claim 69, wherein said continuum divider comprises a user-selectable number of sliders operable to be moved by a user to said user-selectable points.

76. A device according to claim 67, wherein said category definer comprises a facility for associating a color with a category that is defined and wherein said device is operable to display regions that have been associated with a given category on said continuum using said associated color.

77. A device according to claim 67, further comprising an overlay unit for displaying said continuum in association with data connected with said parameter, thereby to assist in selection of said points.

78. A device according to claim 77, wherein said overlay unit is a graphical overlay unit operable to display said continuum in association with data connected with said parameter and graphically arranged and scaled according to said continuum.

79. A method of associating a series of outputs with detected levels of a plurality of continuously varying parameters, said detected levels comprising an outcome, the method comprising

setting one or more boundary levels for each parameter, thereby defining regions between each boundary level,

associating categorization labels with each said defined region,

associating rules with each region and with combinations of regions of different parameters to associate a series of outputs with said regions and combinations, such that at least one of said series of outputs is produced by an outcome.

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80. A method according to claim 79, wherein at least one of said parameters is a body measurement and said output is a medical instruction.

81. A medical measurement categorization system comprising:

a multiplicity of body measurement devices disposed in user locations and being connected via one or more networks to at least one controller computer remote from at least one of said user locations, said controller computer being equipped with a unified messaging facility to respond in a form suitable for different forms of network;

personal parameter measuring software resident on at least one data processing device for processing data output of at least one of said body measurement devices;

personal parameter categorization software resident on at least one of said data processing devices and said at least one controller computer for categorizing data output of at least one of said body measurement devices; and

output means for outputting an indication of said categorized data.

82. A medical measurement categorization system according to claim 81, wherein said categorization software is operable to supply primary categorizations to individual measurements and a secondary categorization to combinations of said primary categorization.

83. A medical measurement categorization system according to claim 81, comprising a memory for storing measurements and a comparator for comparing a current measurement with at least one corresponding stored measurement, wherein said categorization software is operative to apply a categorization to said current measurement based on the change between said current measurement and said at least one stored measurement.

84. A medical measurement categorization system according to claim 81, comprising an input device for inputting boundary values of measurable parameters to define said categories.

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85. A medical measurement categorization system according to claim 82, comprising an input device for inputting boundary values of measurable parameters to define said primary categories and for inputting combination rules for combinations of said primary categories to define said secondary categories.

86. A system according to claim 56, wherein said measurement is inputtable to said system over a telephone via sound recognition apparatus able to interrogate a user and understand sound responses.

87. A system according to claim 56, comprising a further output device, operable to output measurement data to show at least one of alarms, trends and data patterns.

88. A system according to claim 56, further comprising a unified messaging hierarchy for communicating using a hierarchy of messaging modes.

89. A voicemail system for automatic communication with a user over a telephone network comprising an automatic telephone answering device comprising a sound processor and a data form, wherein said sound processor is operable to ask questions from said form in a voiced manner, to take in answers in sound format, to process said answers and to enter said answers onto said form.

90. A voicemail system according to claim 89, wherein said form is a text form and wherein said sound processor is a text to sound processor.

91. A voicemail system according to claim 89, wherein said sound format is telephone tone format.

92. A voicemail system according to claim 89, wherein said sound format is voice and said sound processor comprises a voice recognition capability.

93. A voicemail system according to claim 92, wherein said sound processor comprises voice to text capability.

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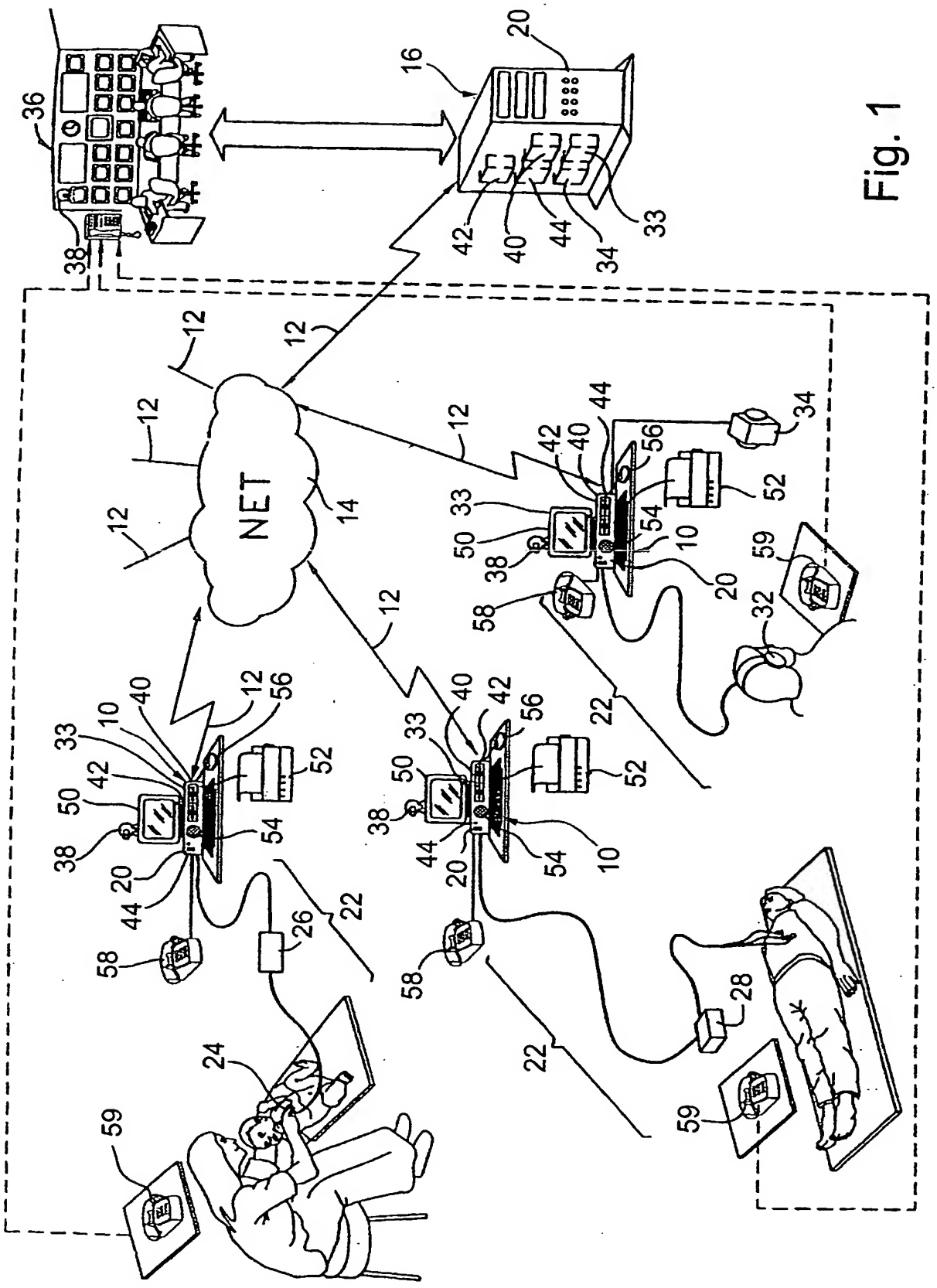

Fig. 1

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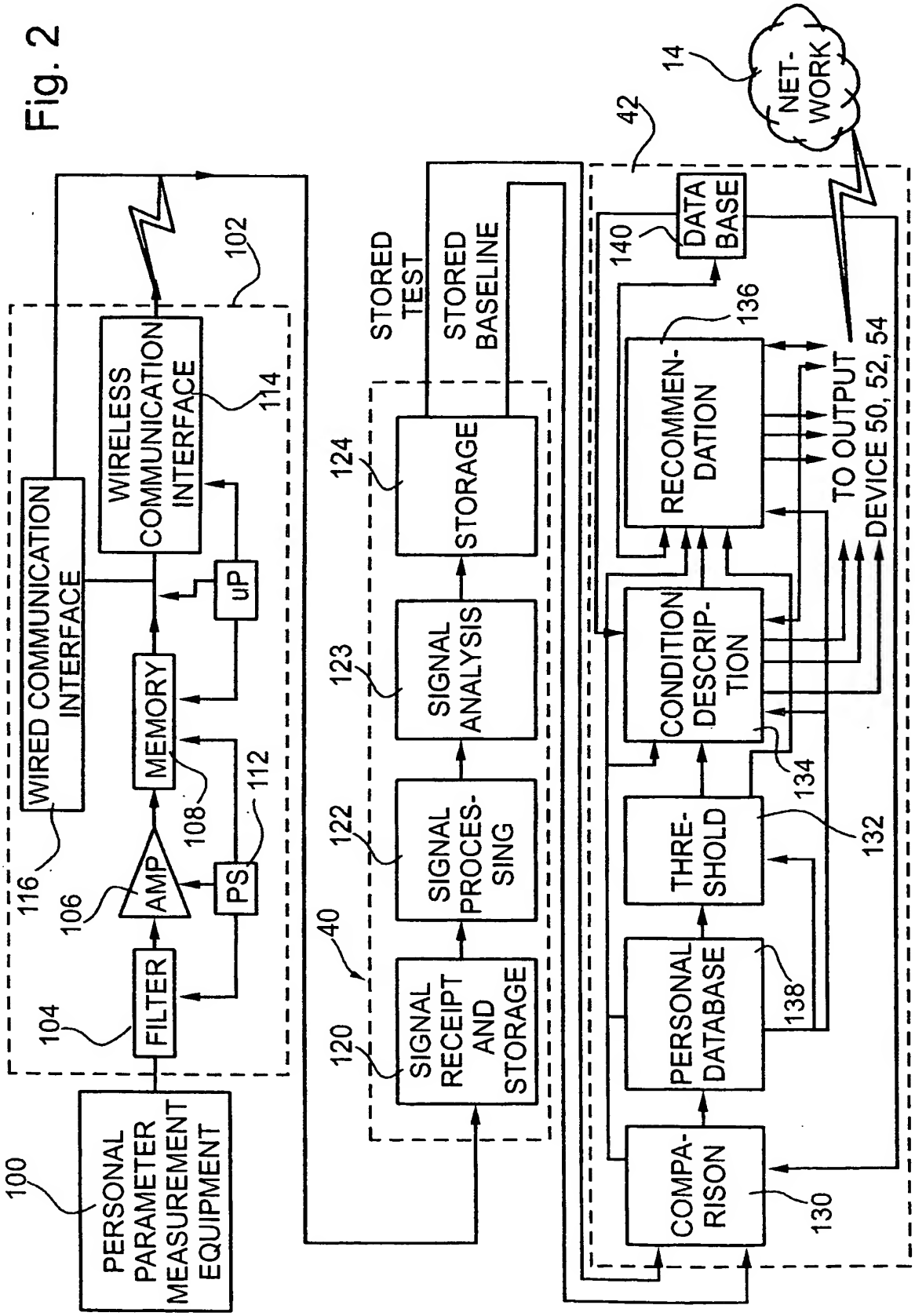
Fig. 2



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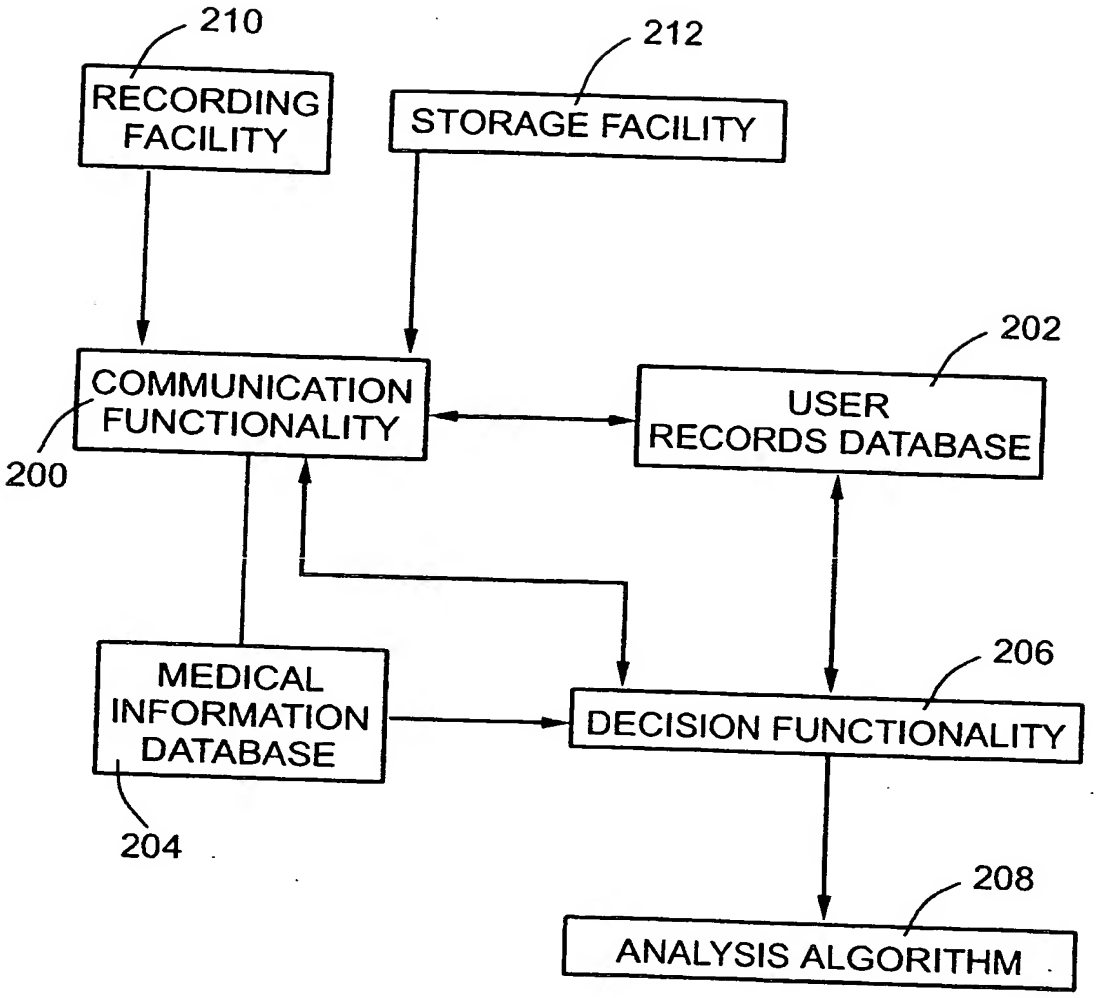

Fig. 3

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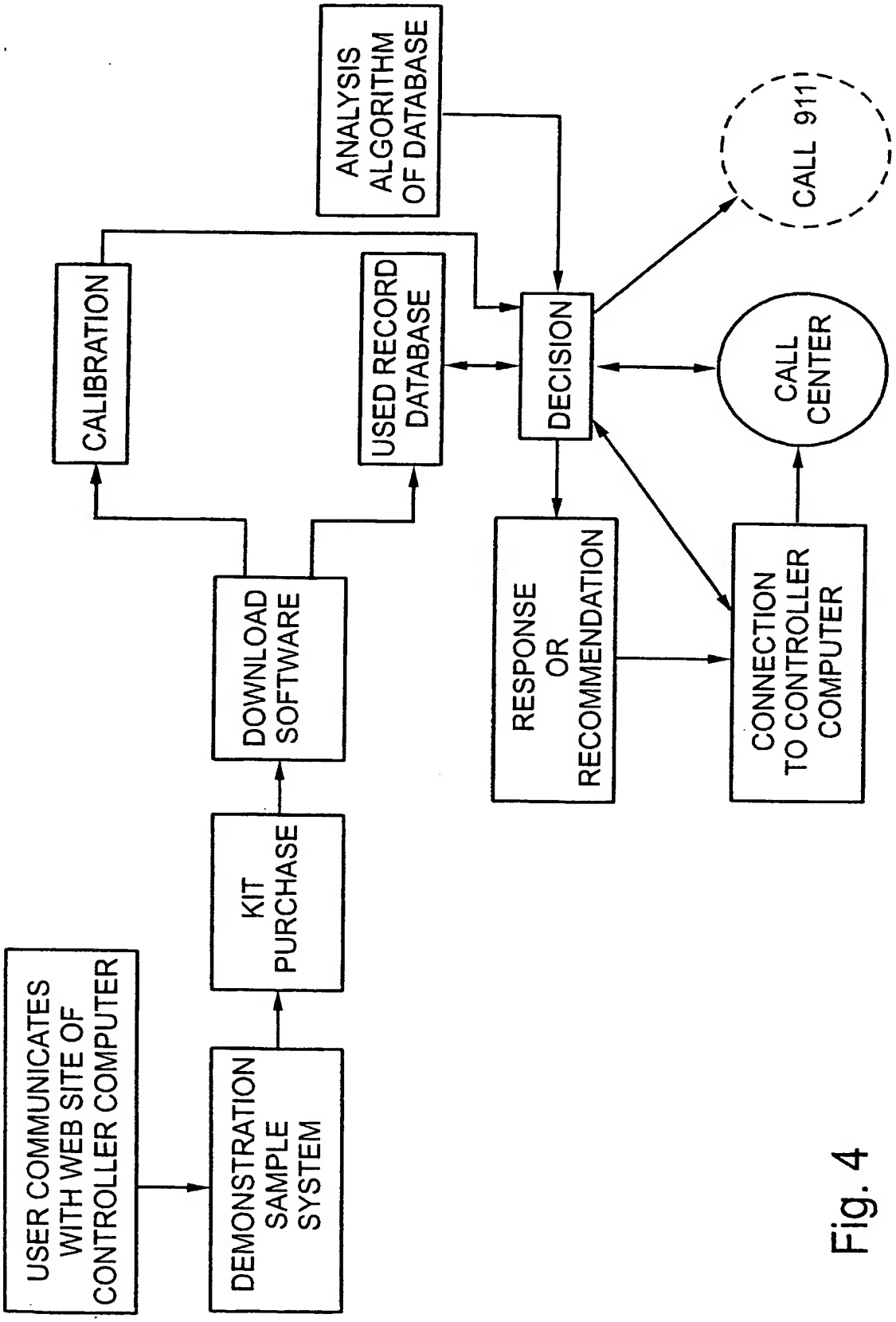

Fig. 4

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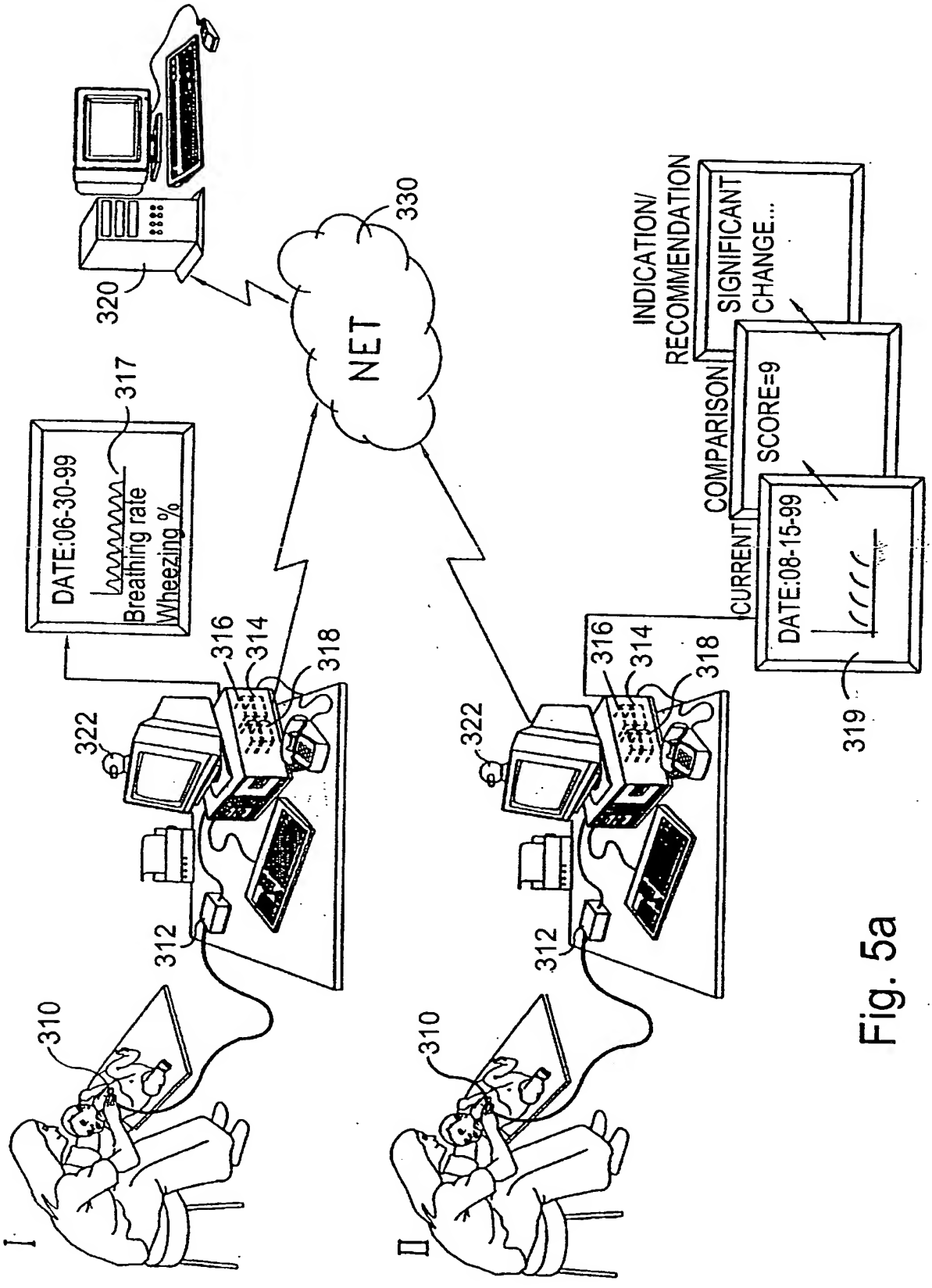

Fig. 5a

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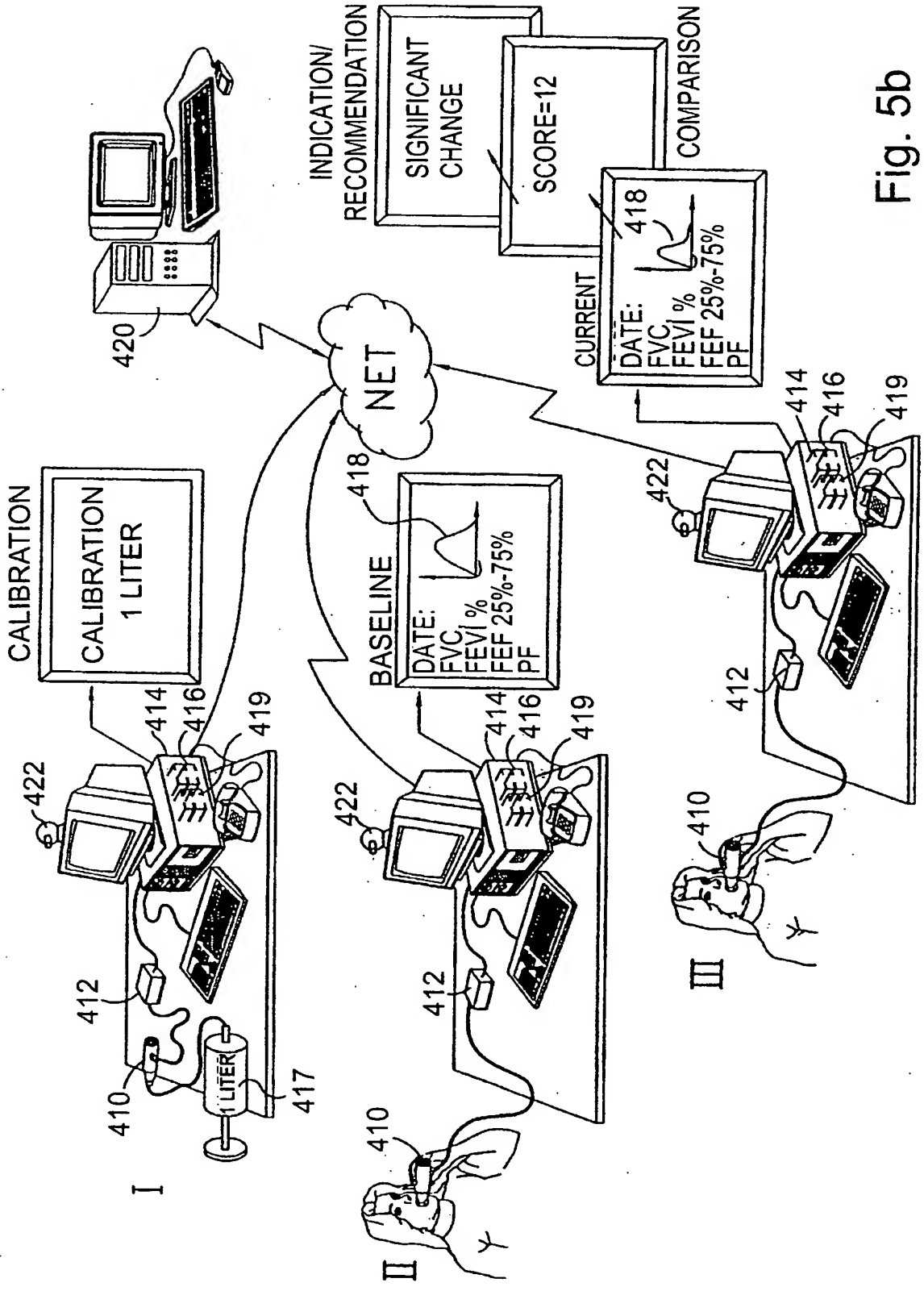

Fig. 5b

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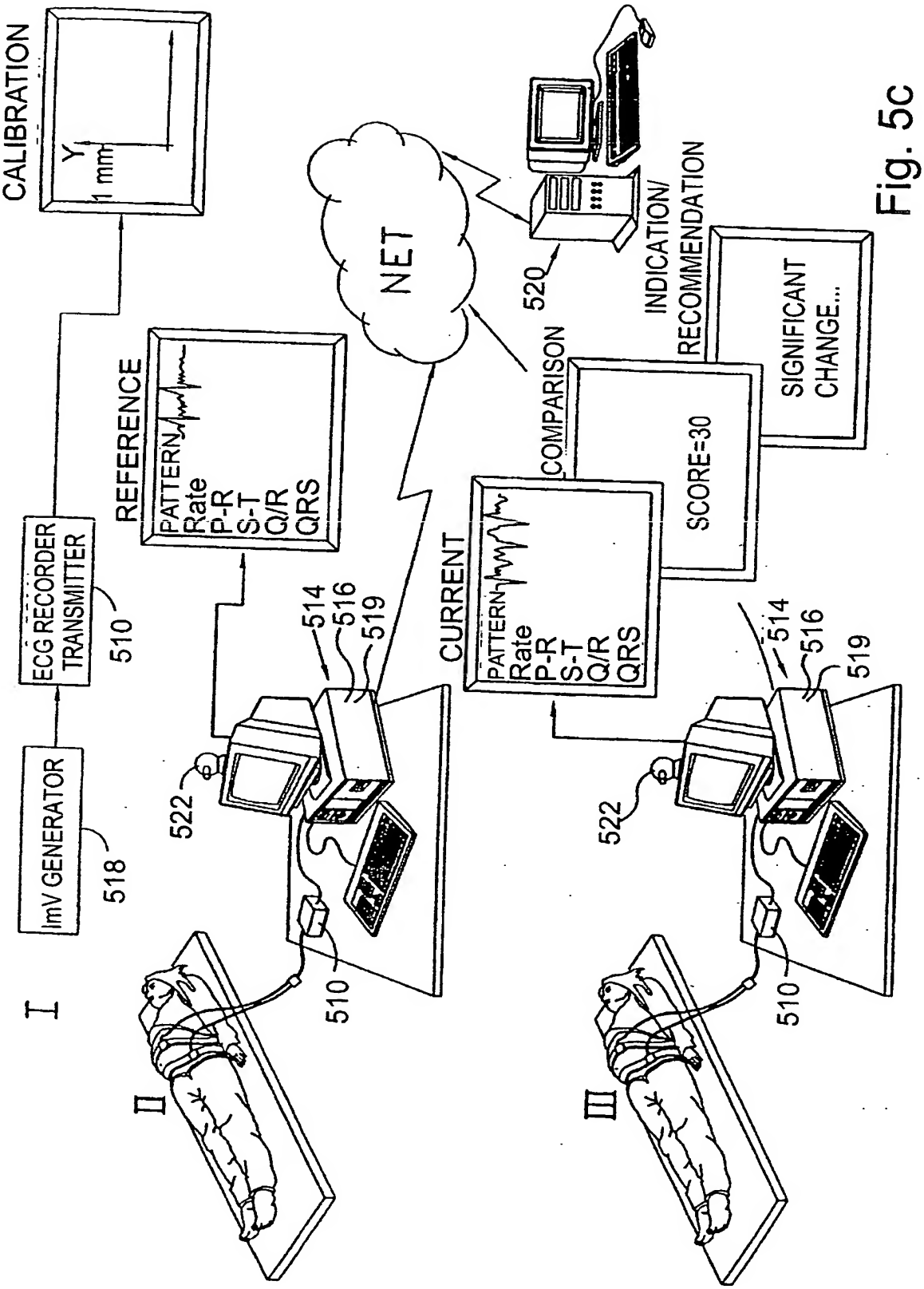

Fig. 5c

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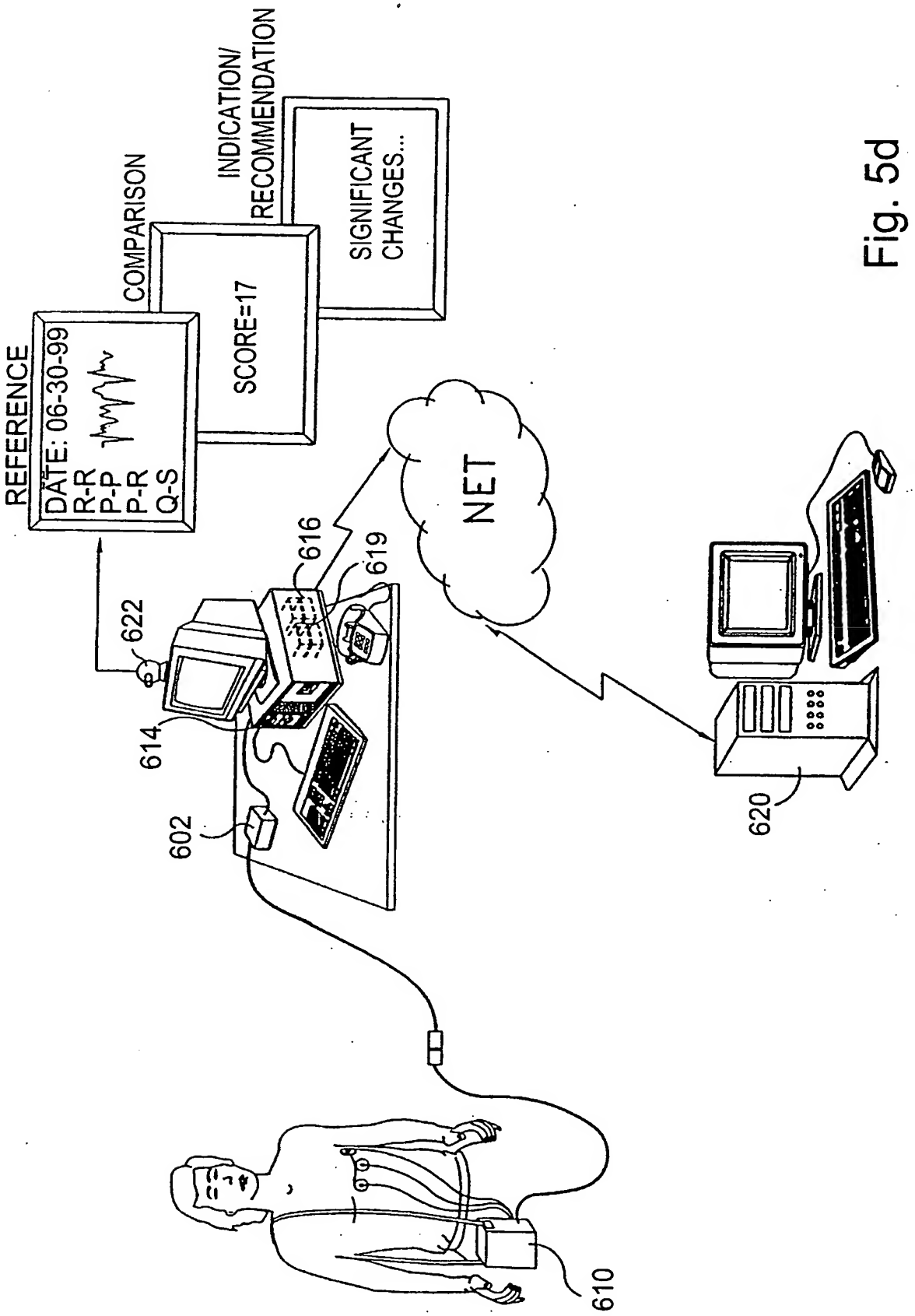

Fig. 5d

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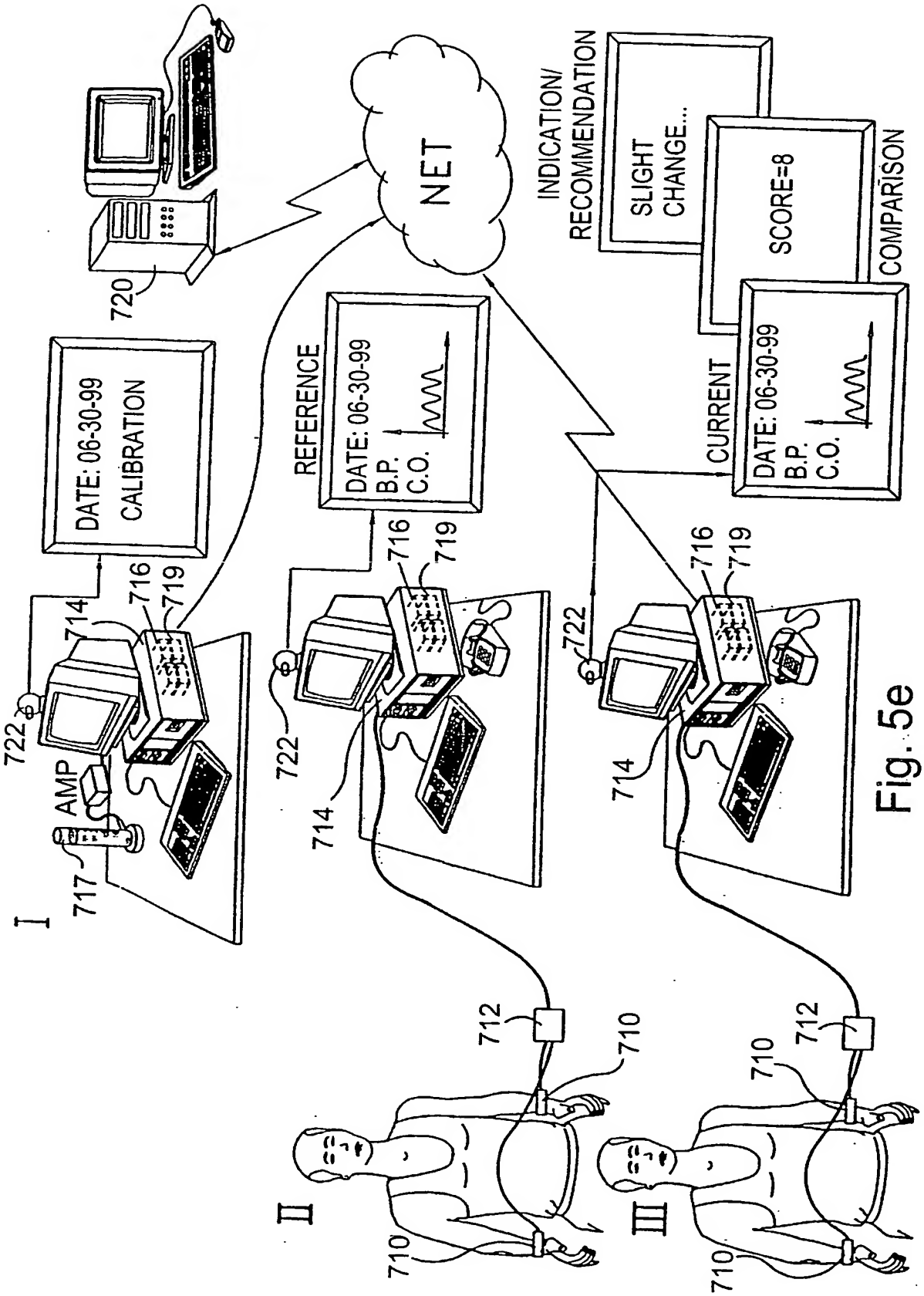

Fig. 5e

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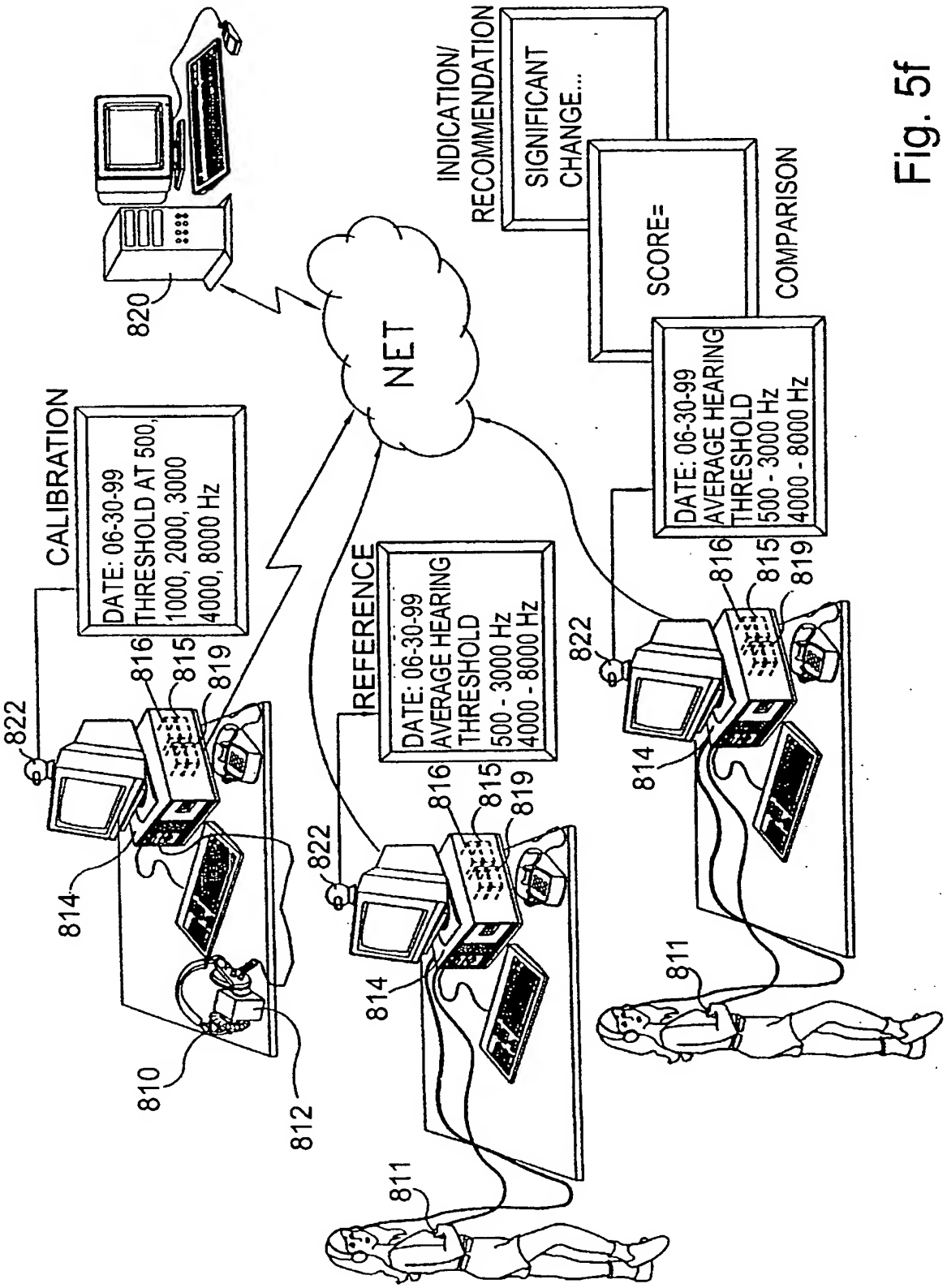

Fig. 5f

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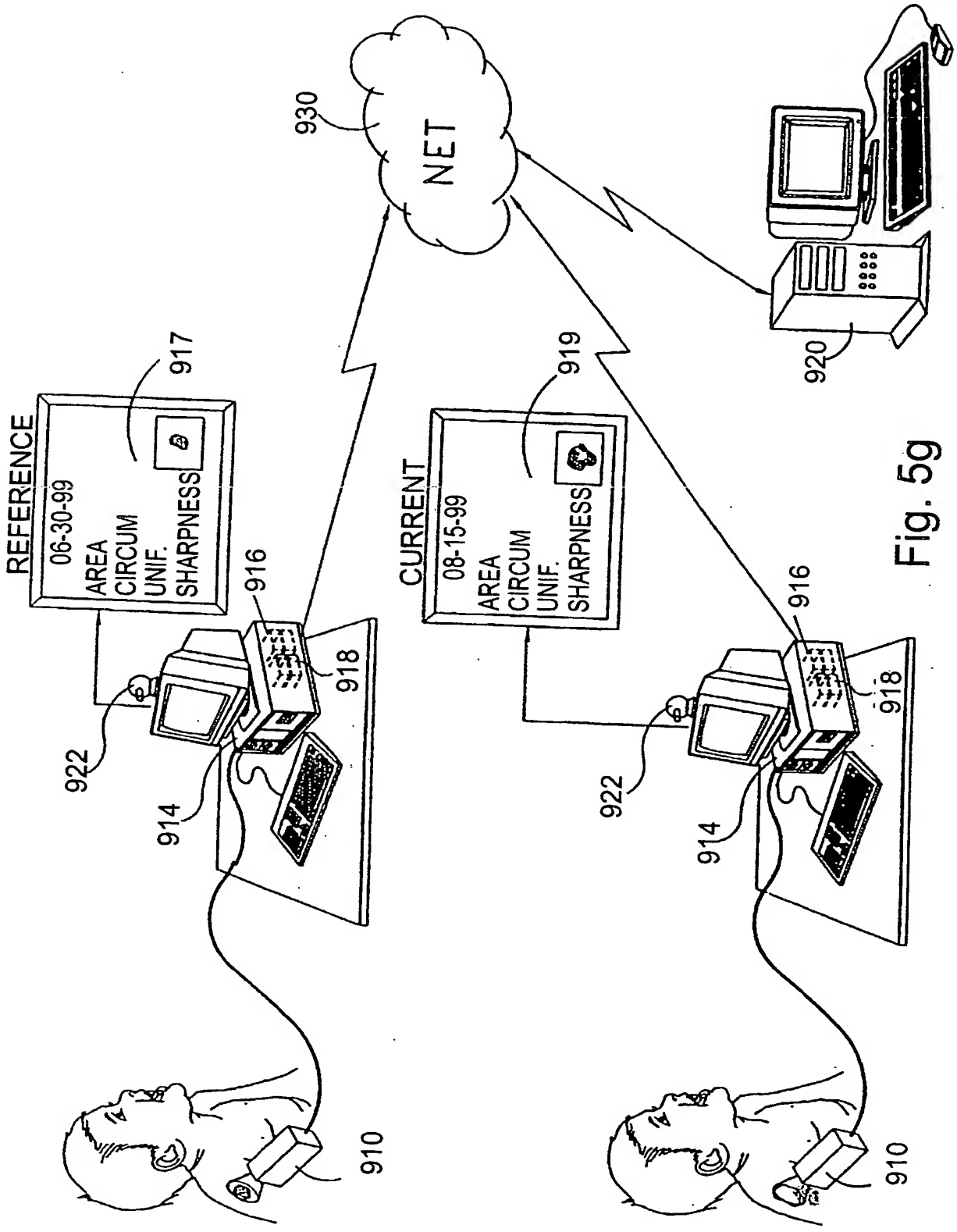

Fig. 5g

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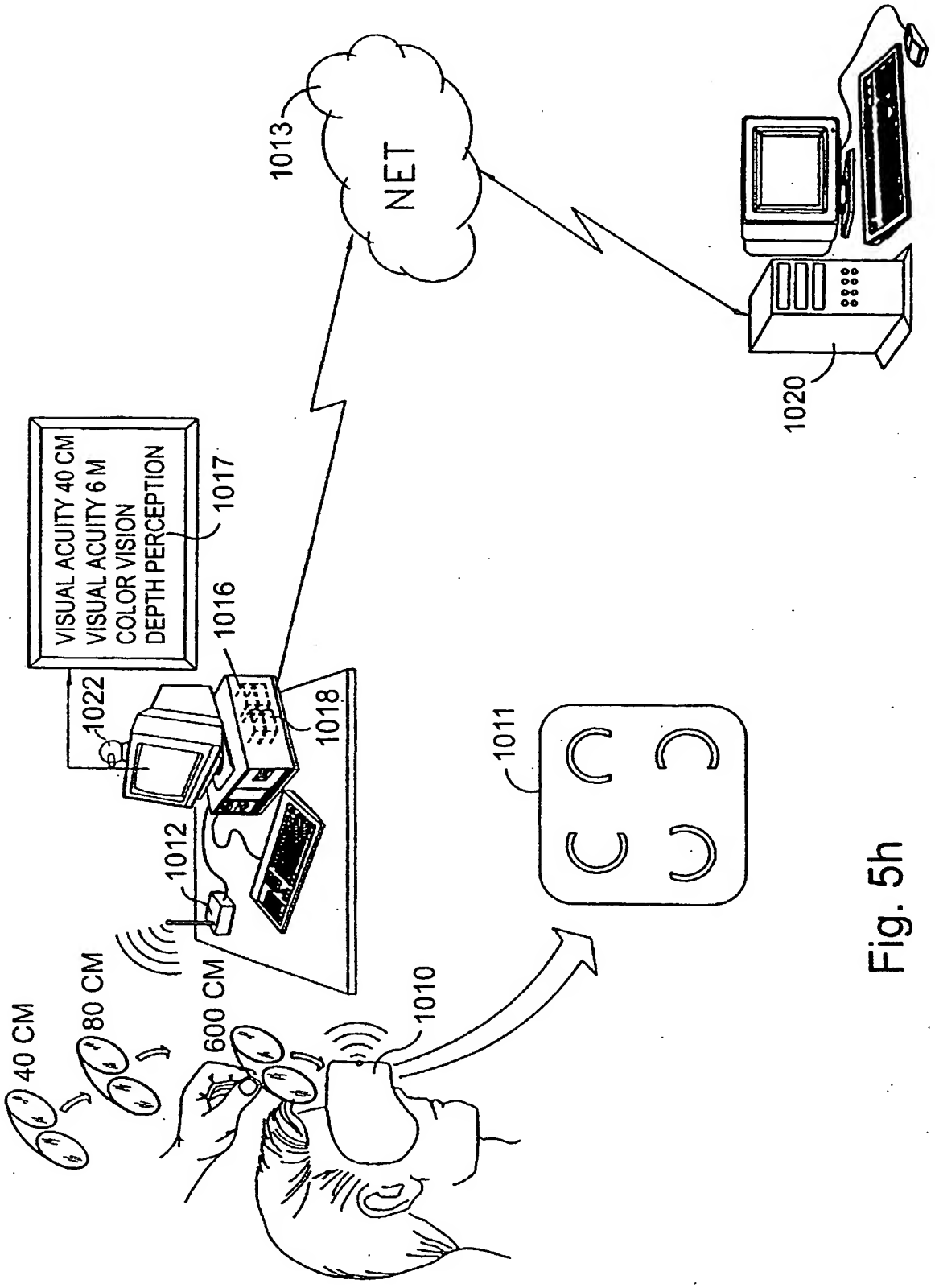

Fig. 5h

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Fig. 6a

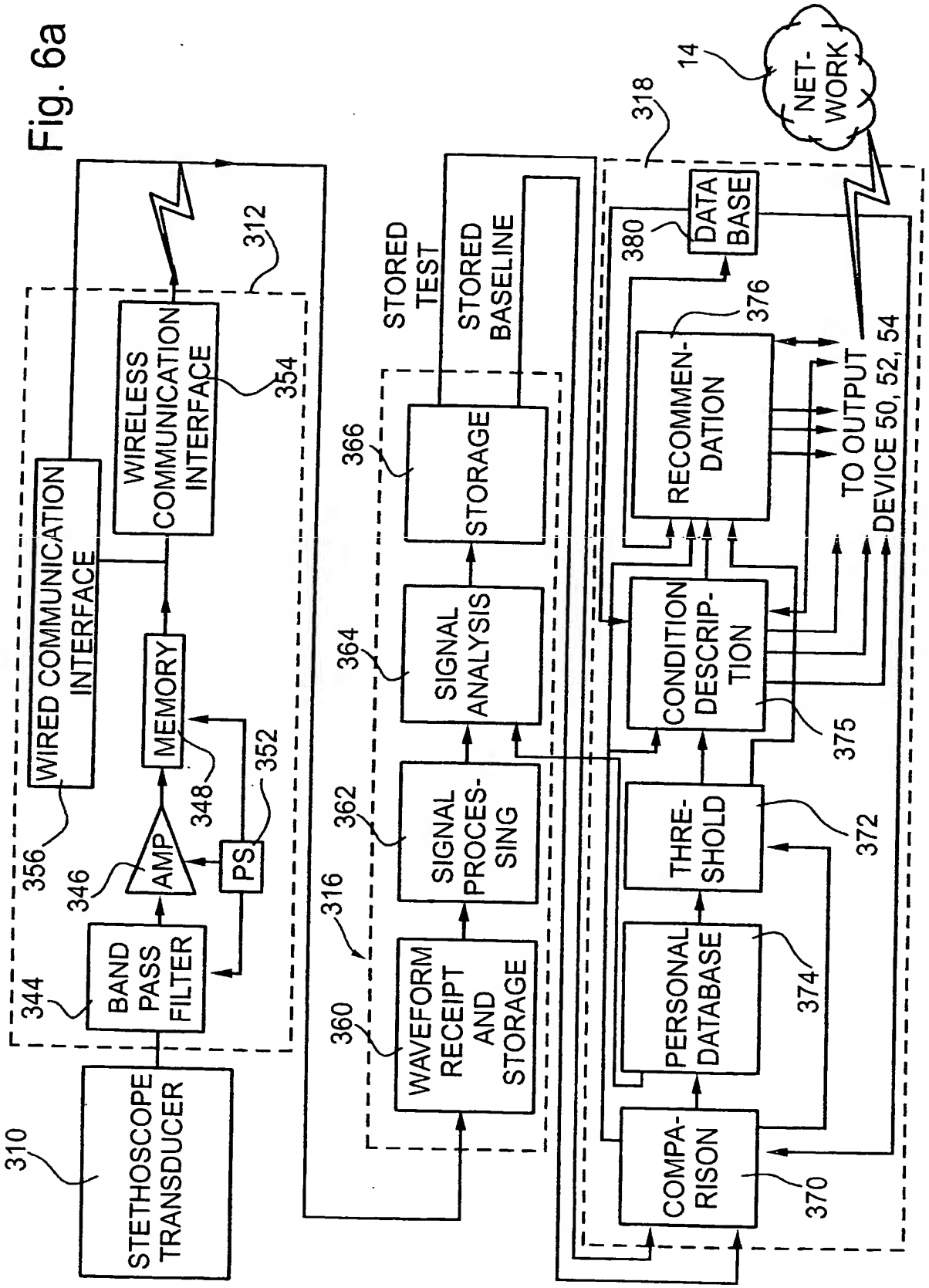

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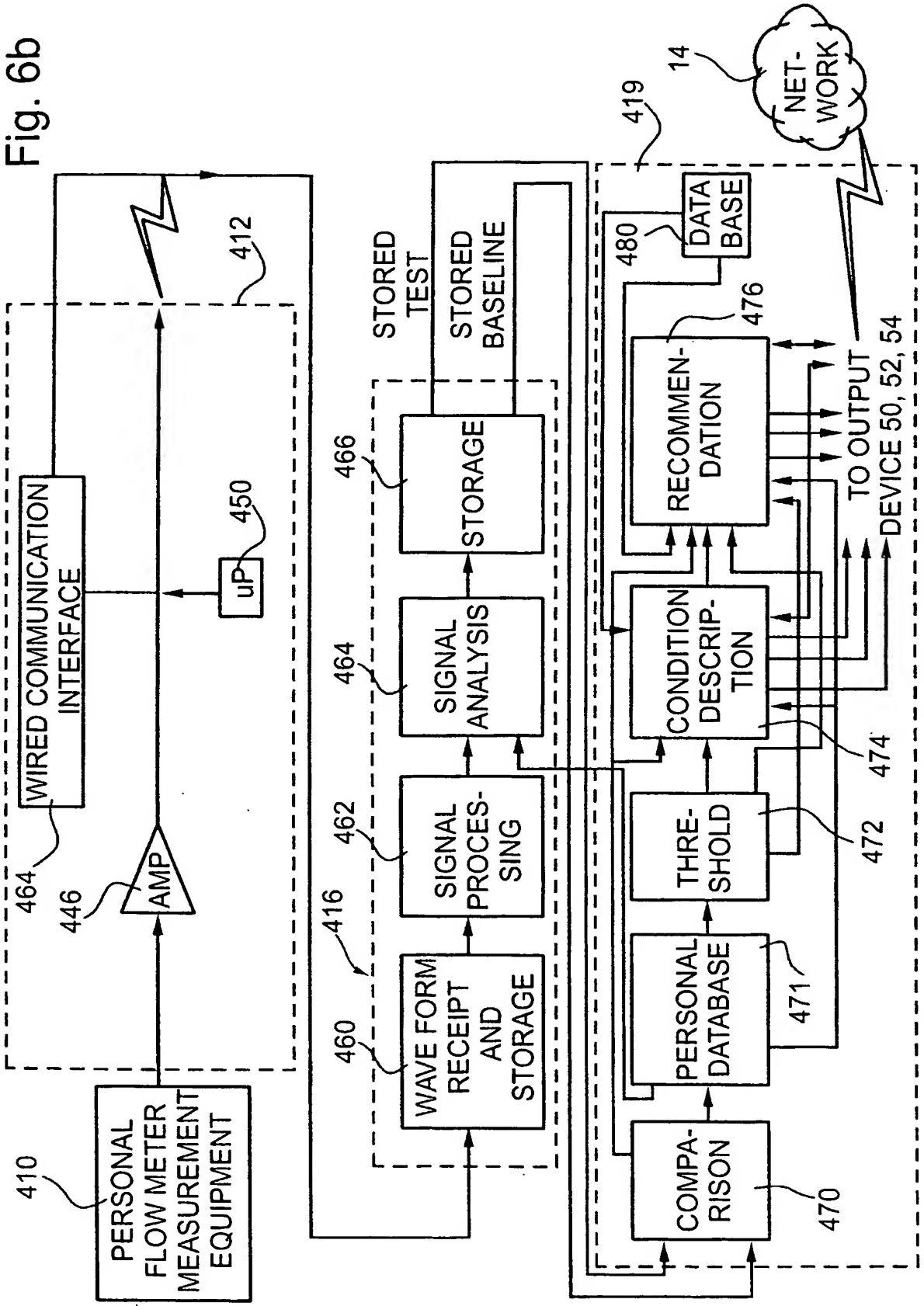
Fig. 6b



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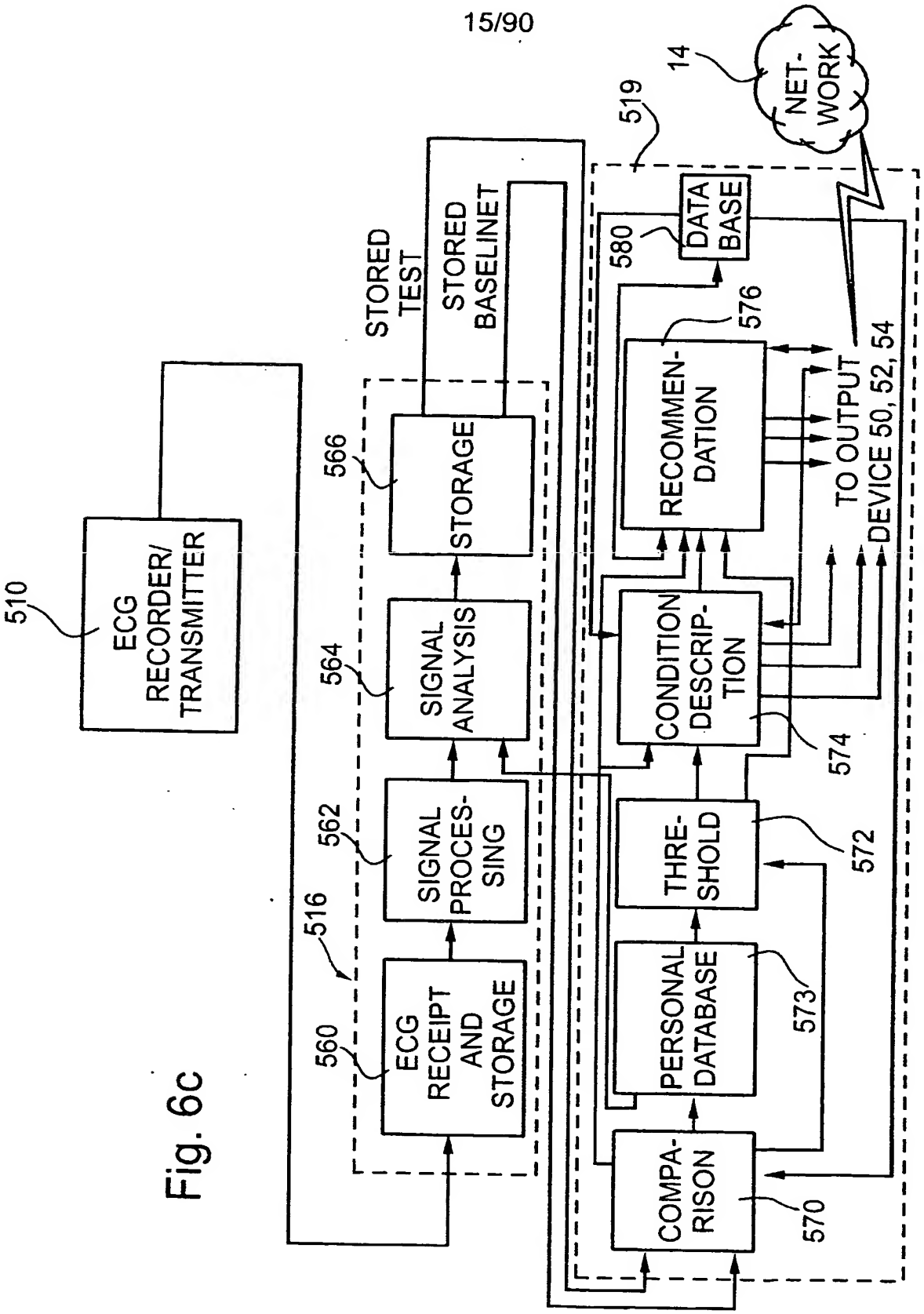

Fig. 6c

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Fig. 6d

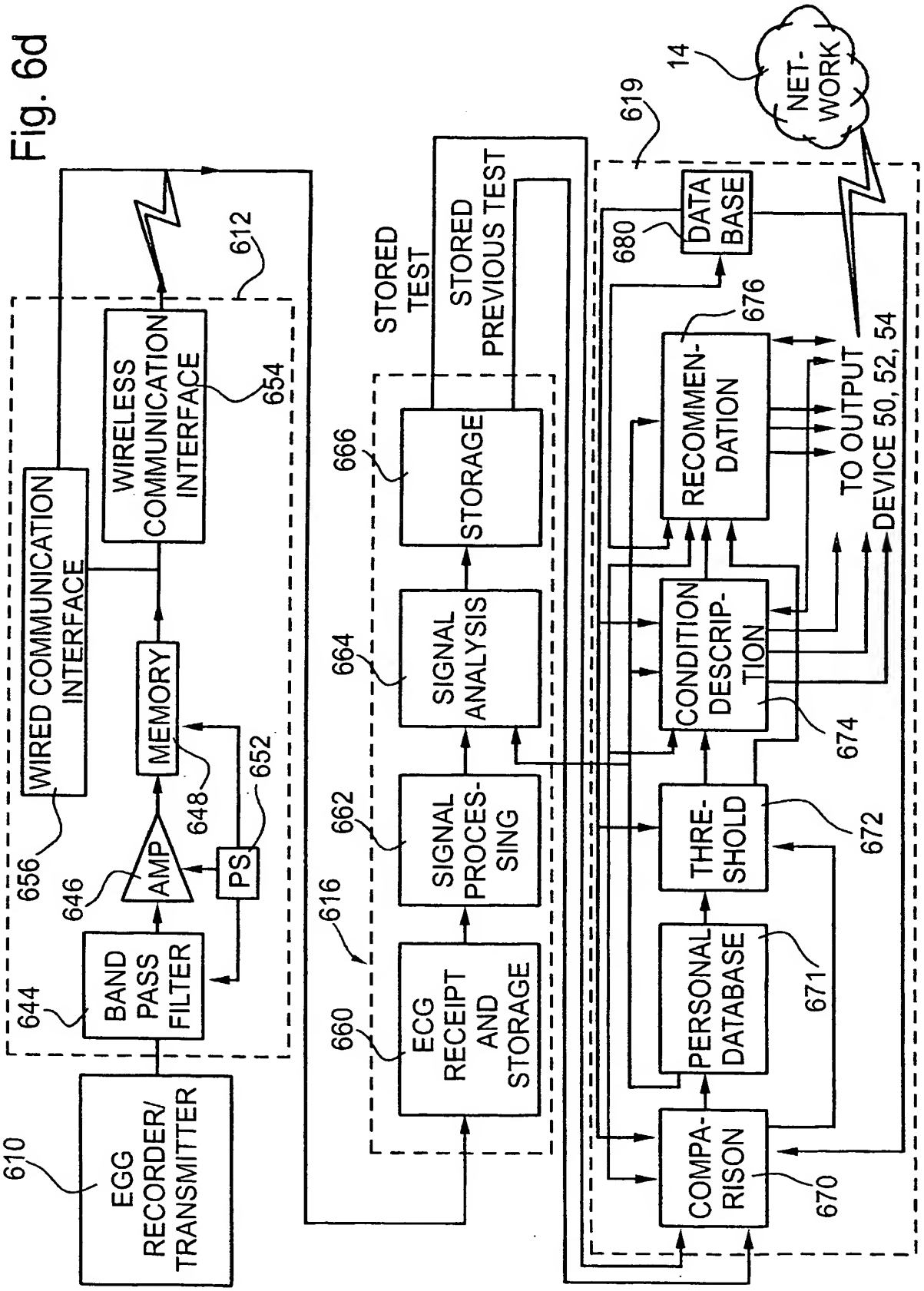

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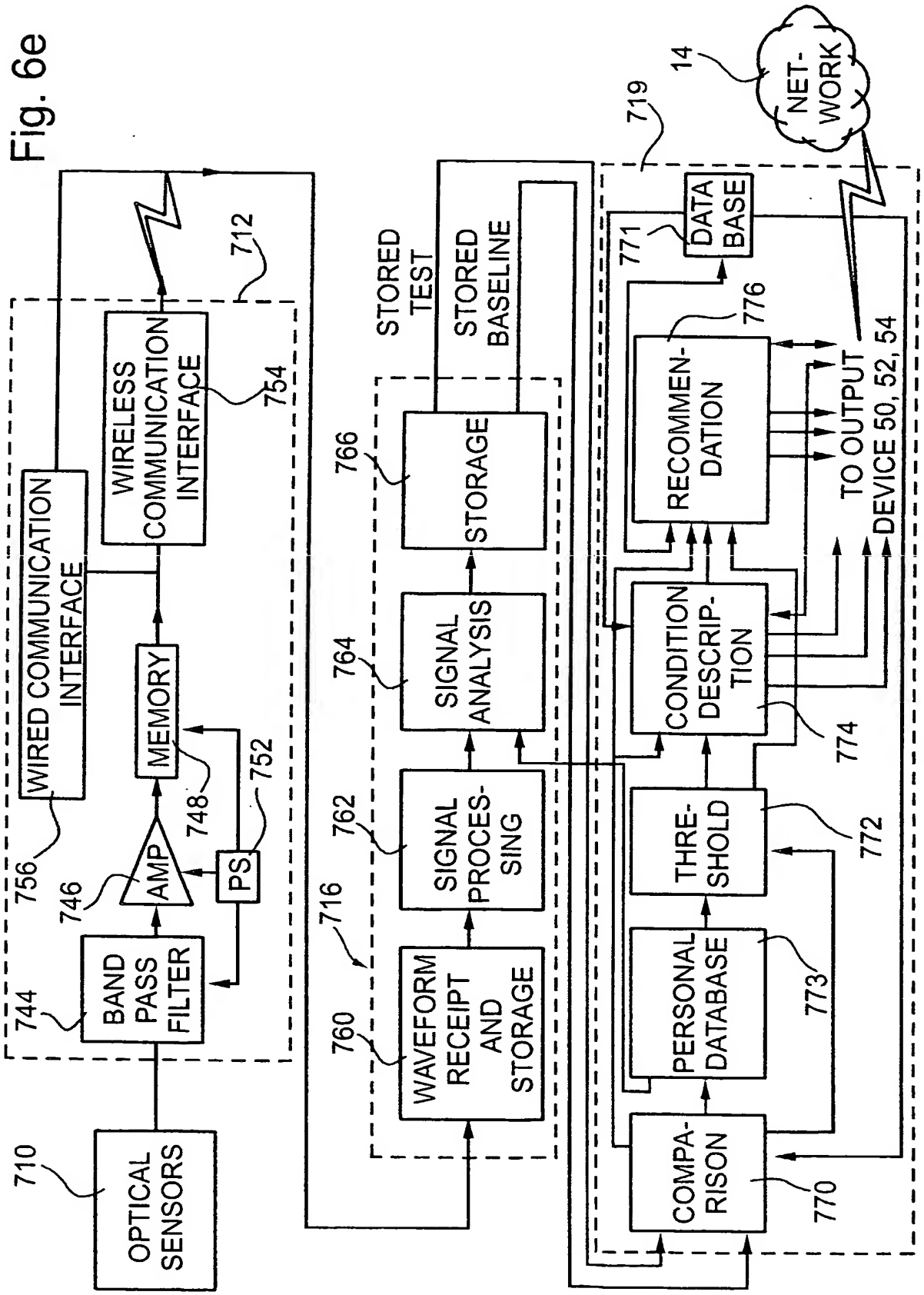
Fig. 6e



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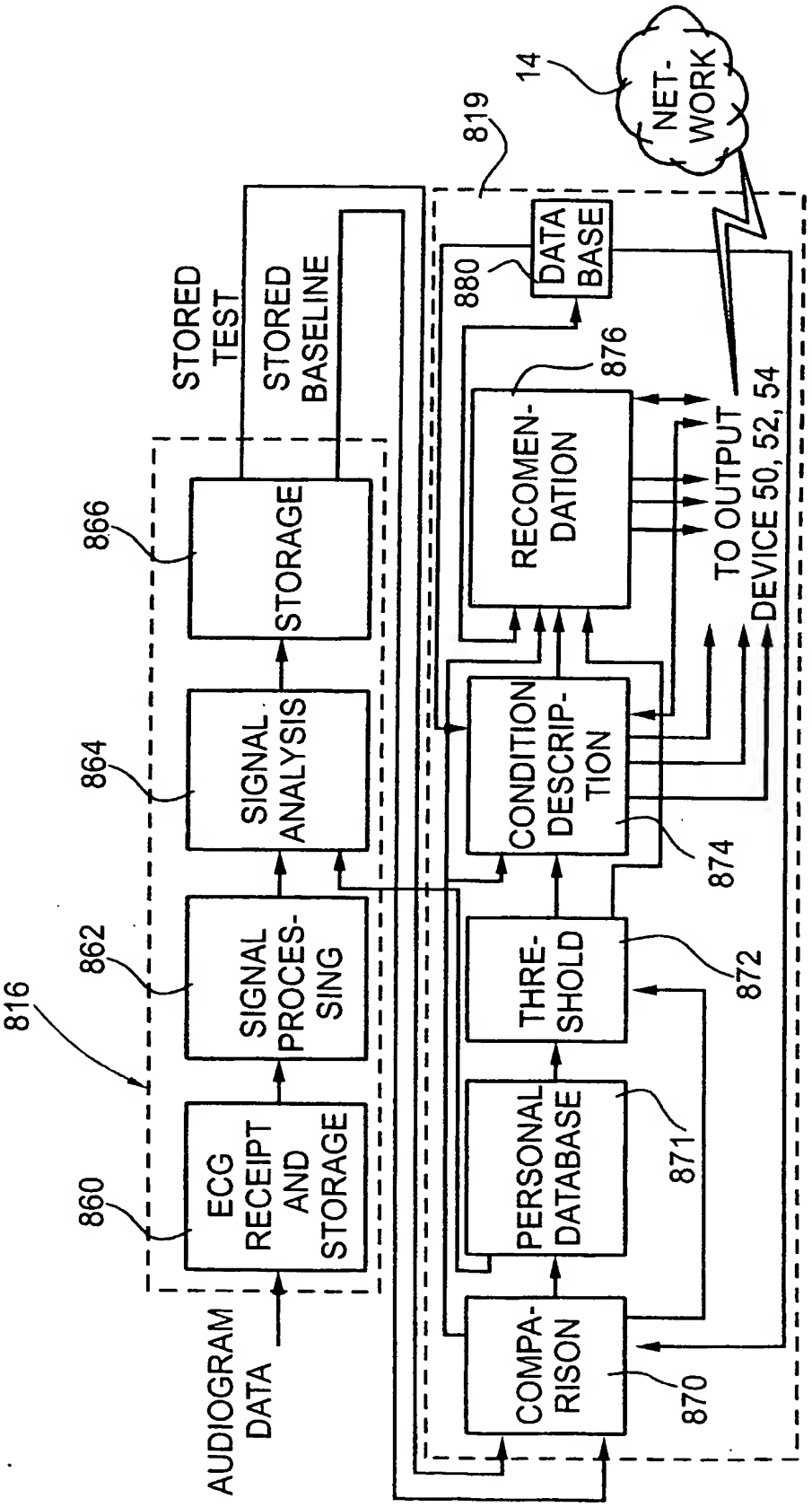

Fig. 6f

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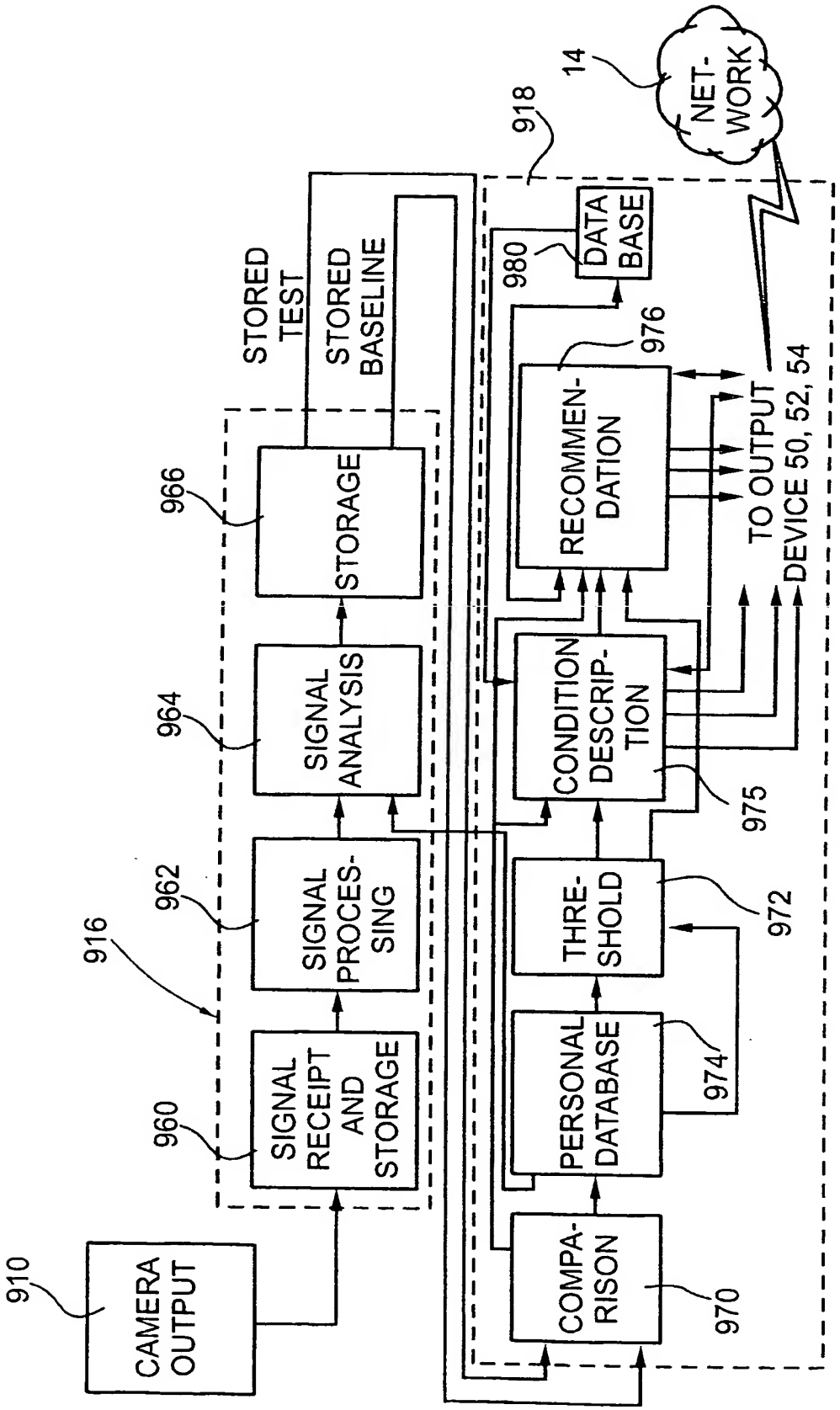

Fig. 6g

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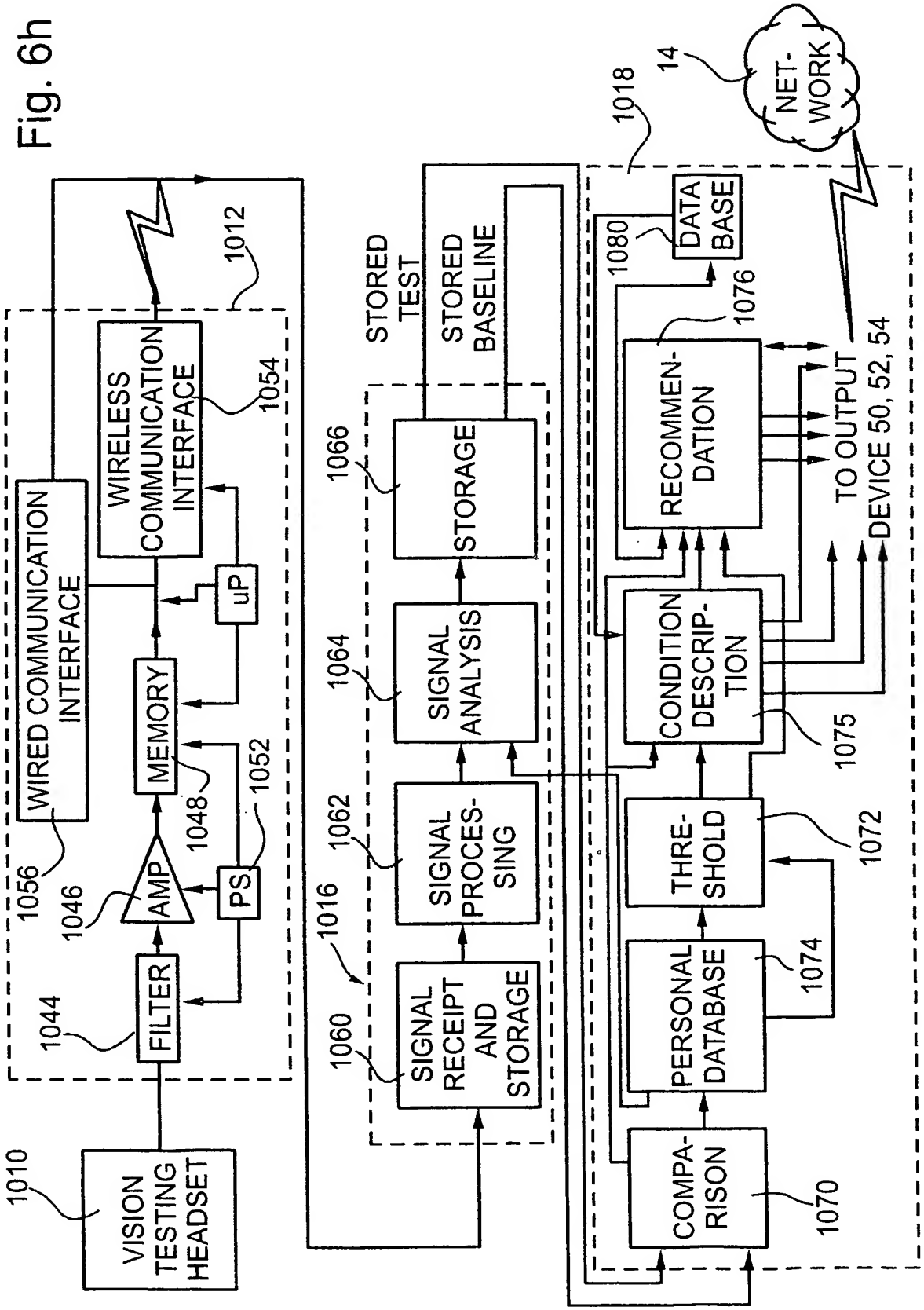
Fig. 6h



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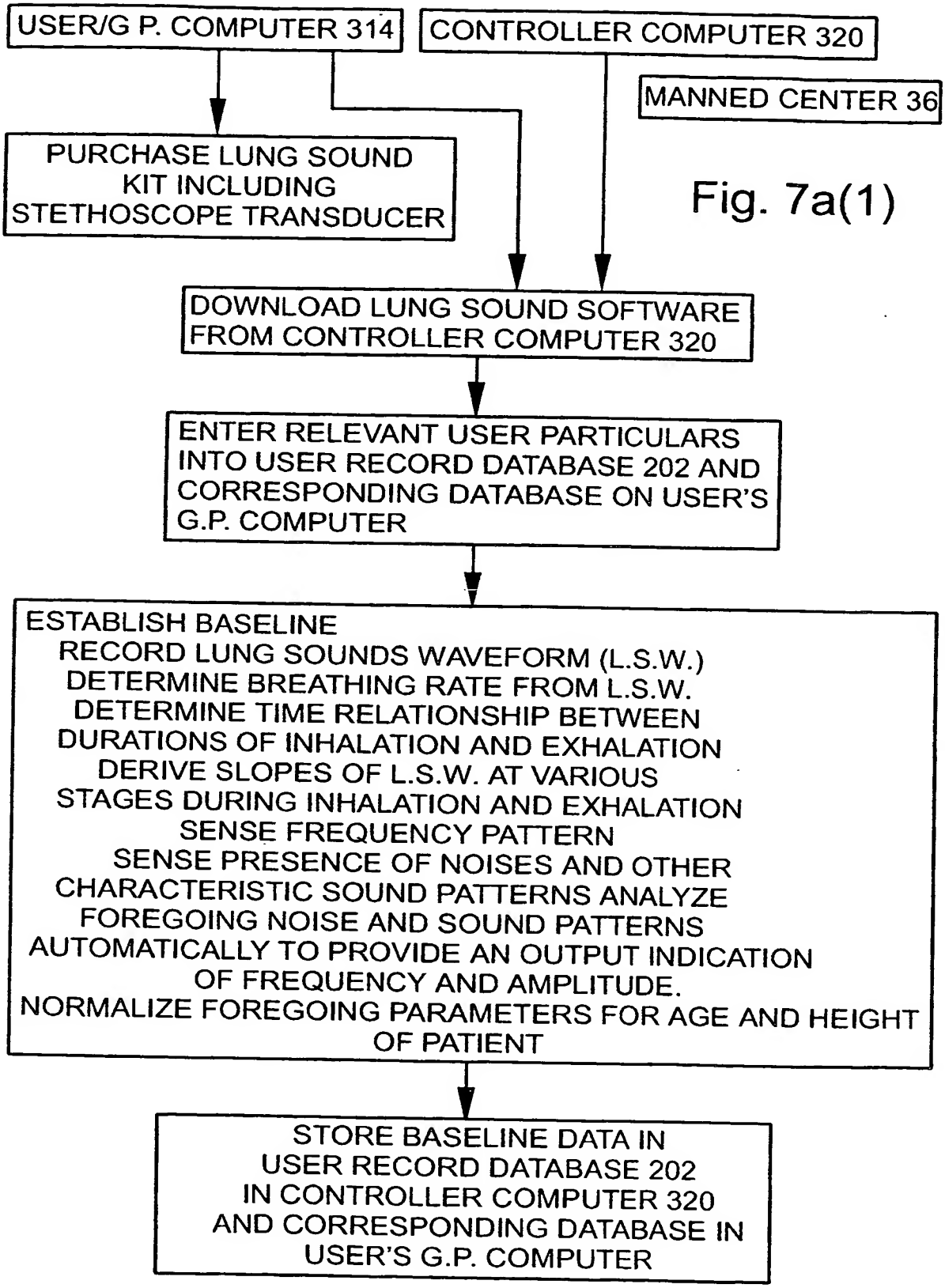

Fig. 7a(1)

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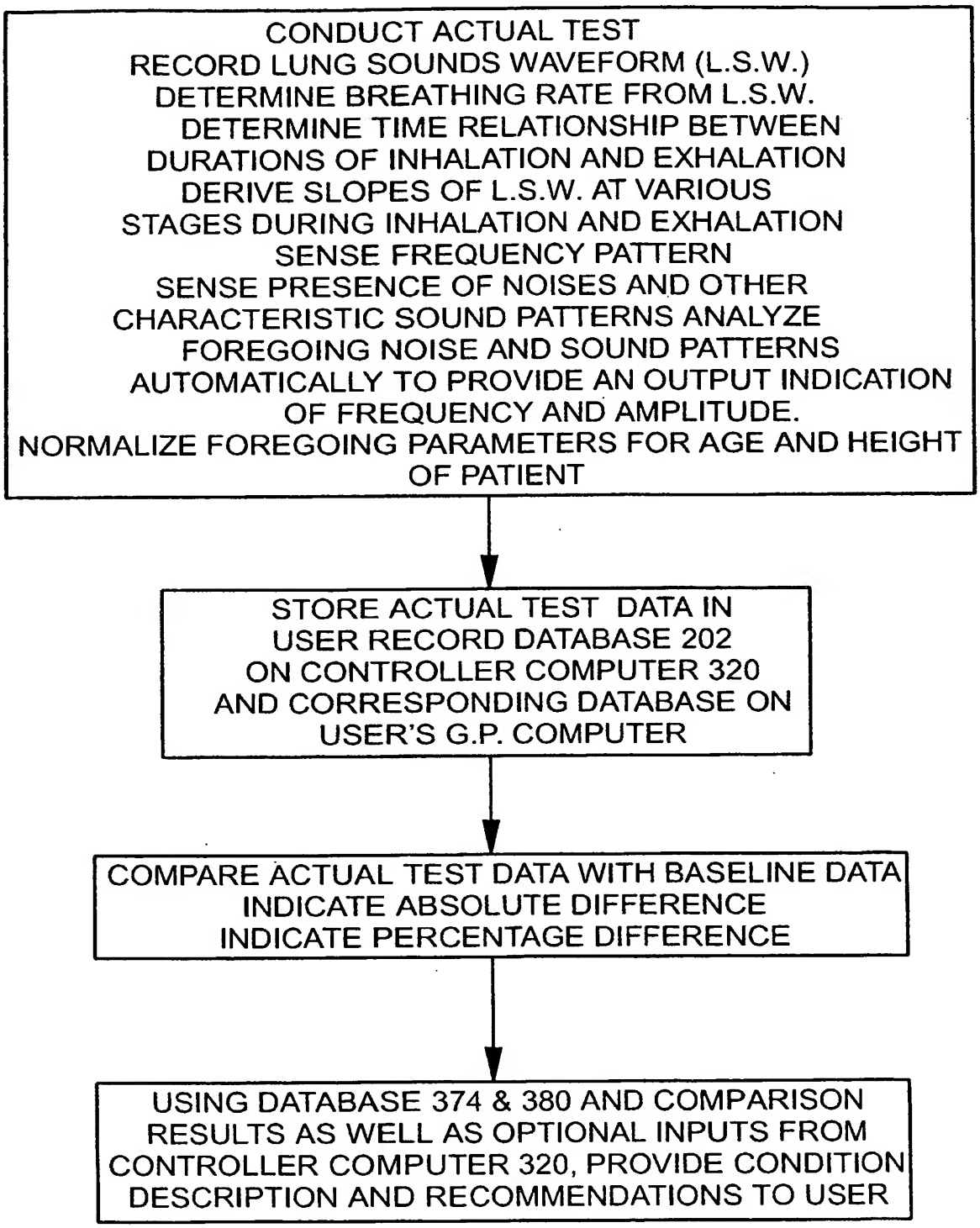

Fig. 7a(2)

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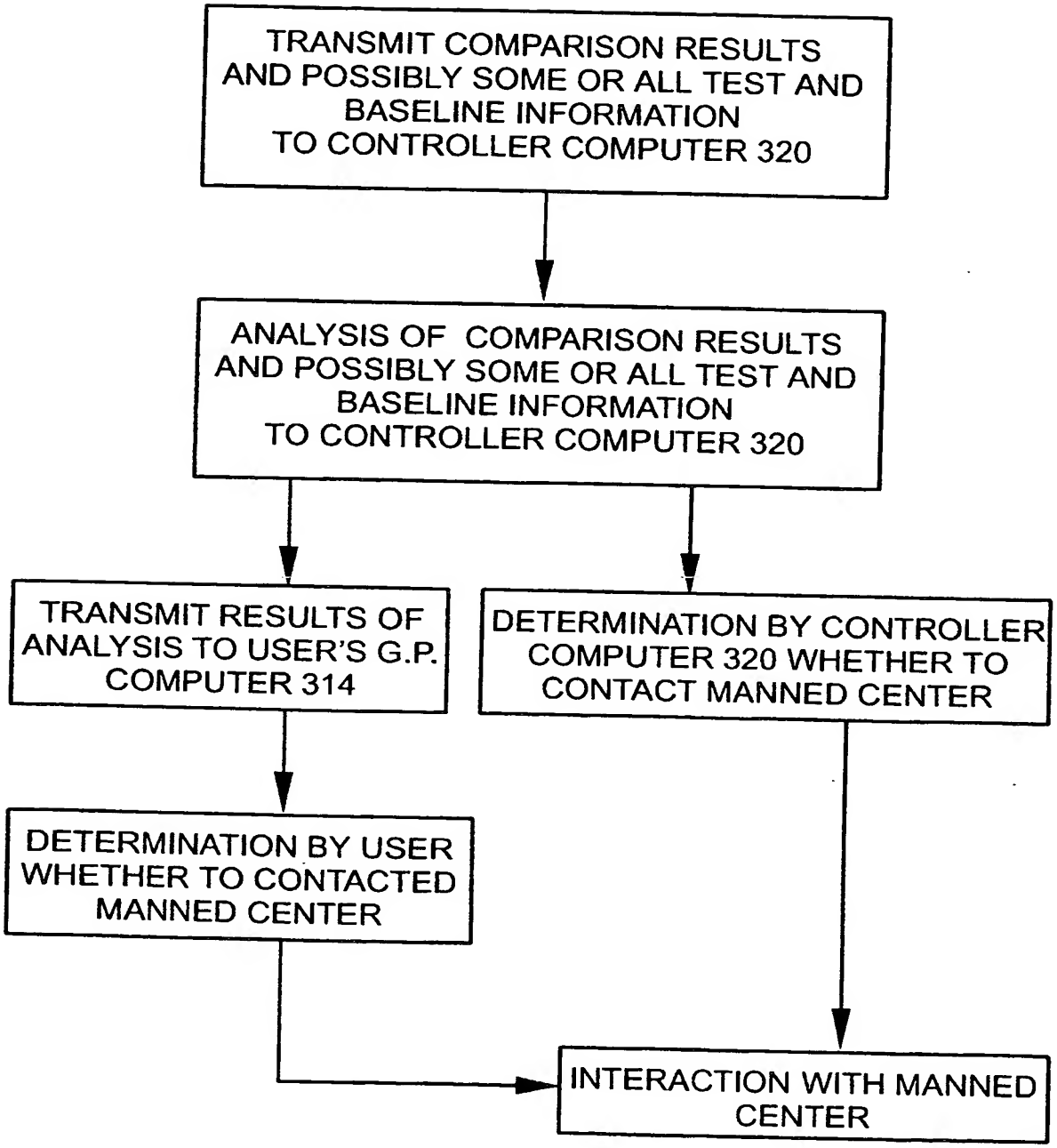

Fig. 7a(3)

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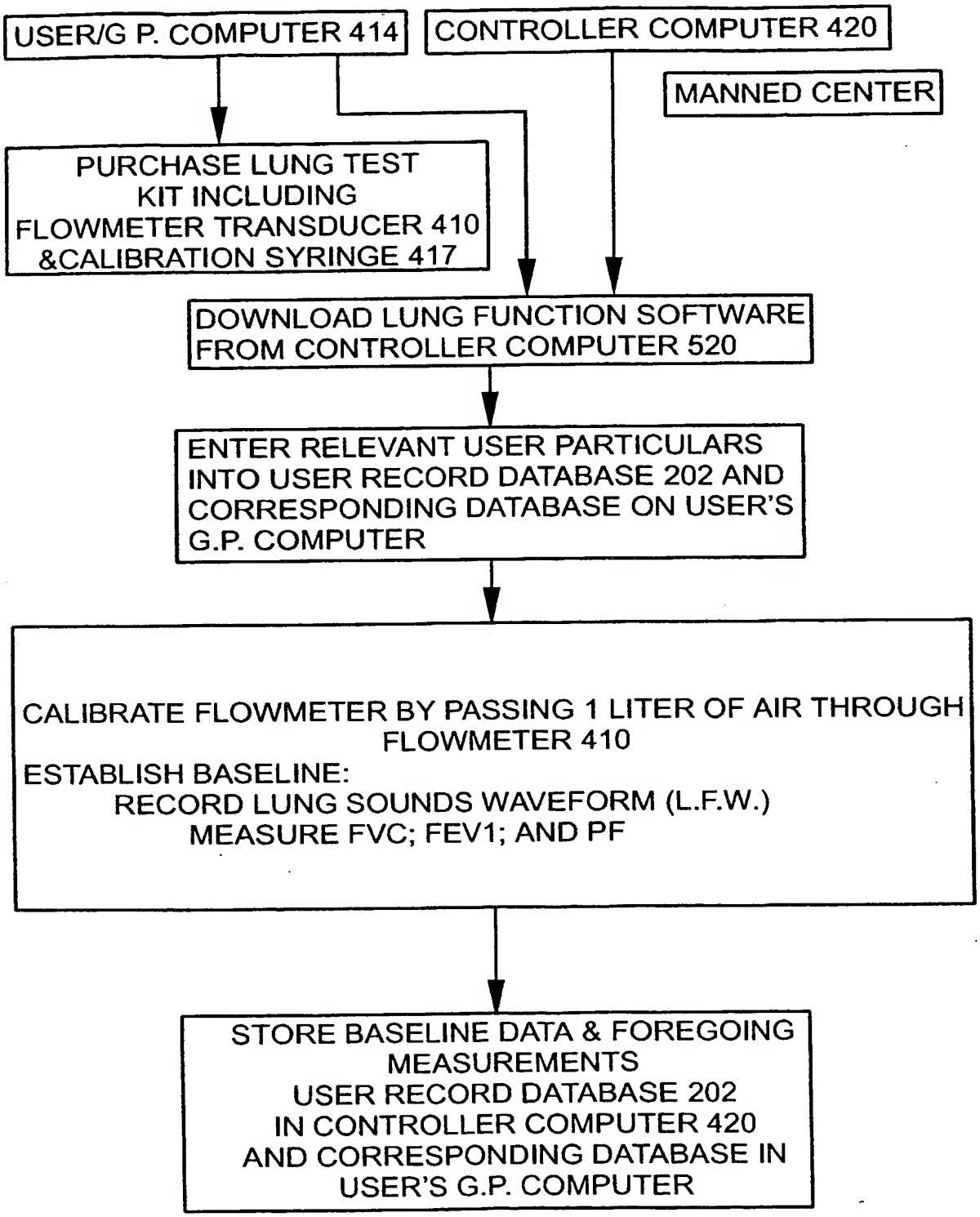

Fig. 7b(1)

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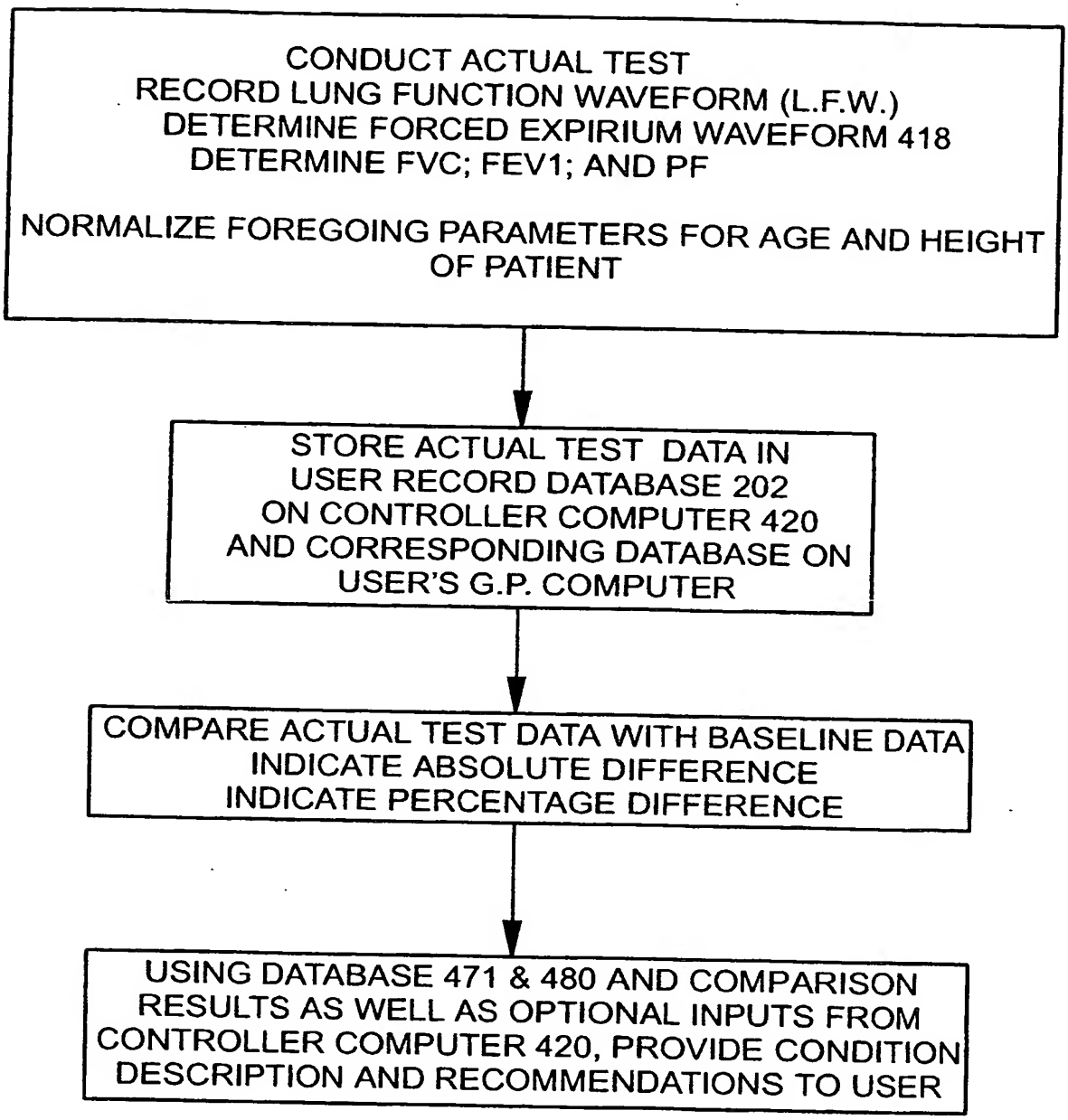

Fig. 7b(2)

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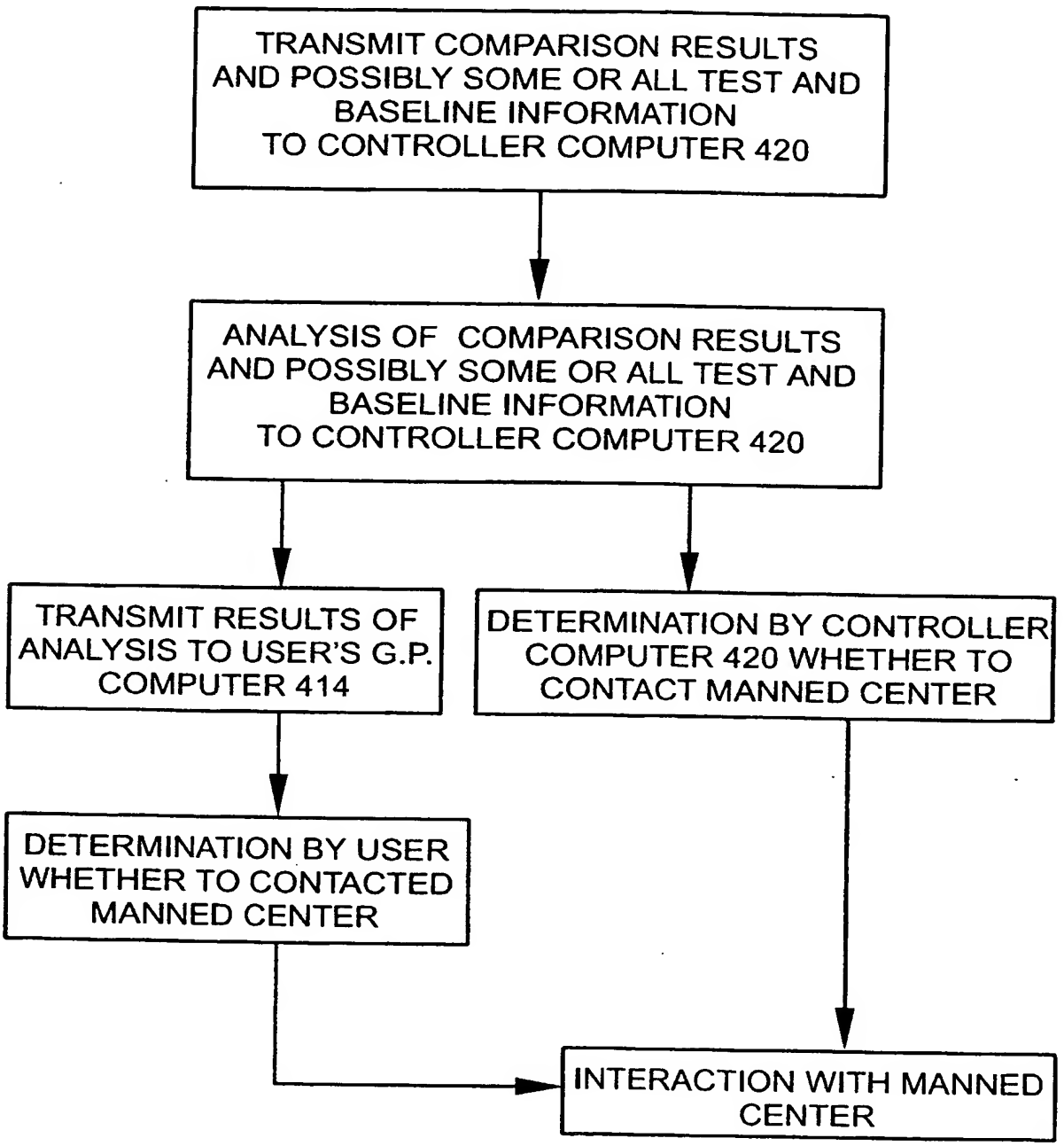

Fig. 7b(3)

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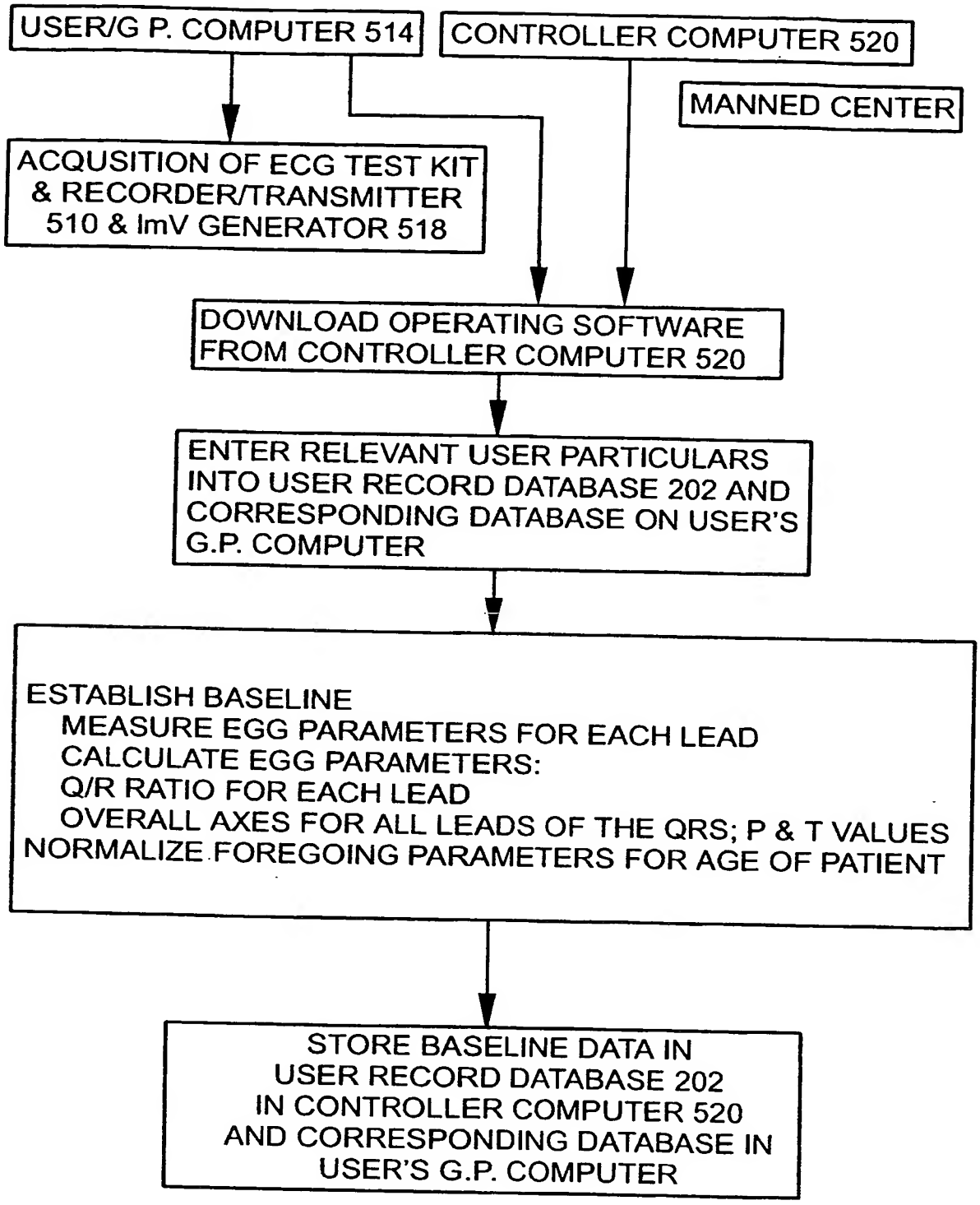

Fig. 7c(1)

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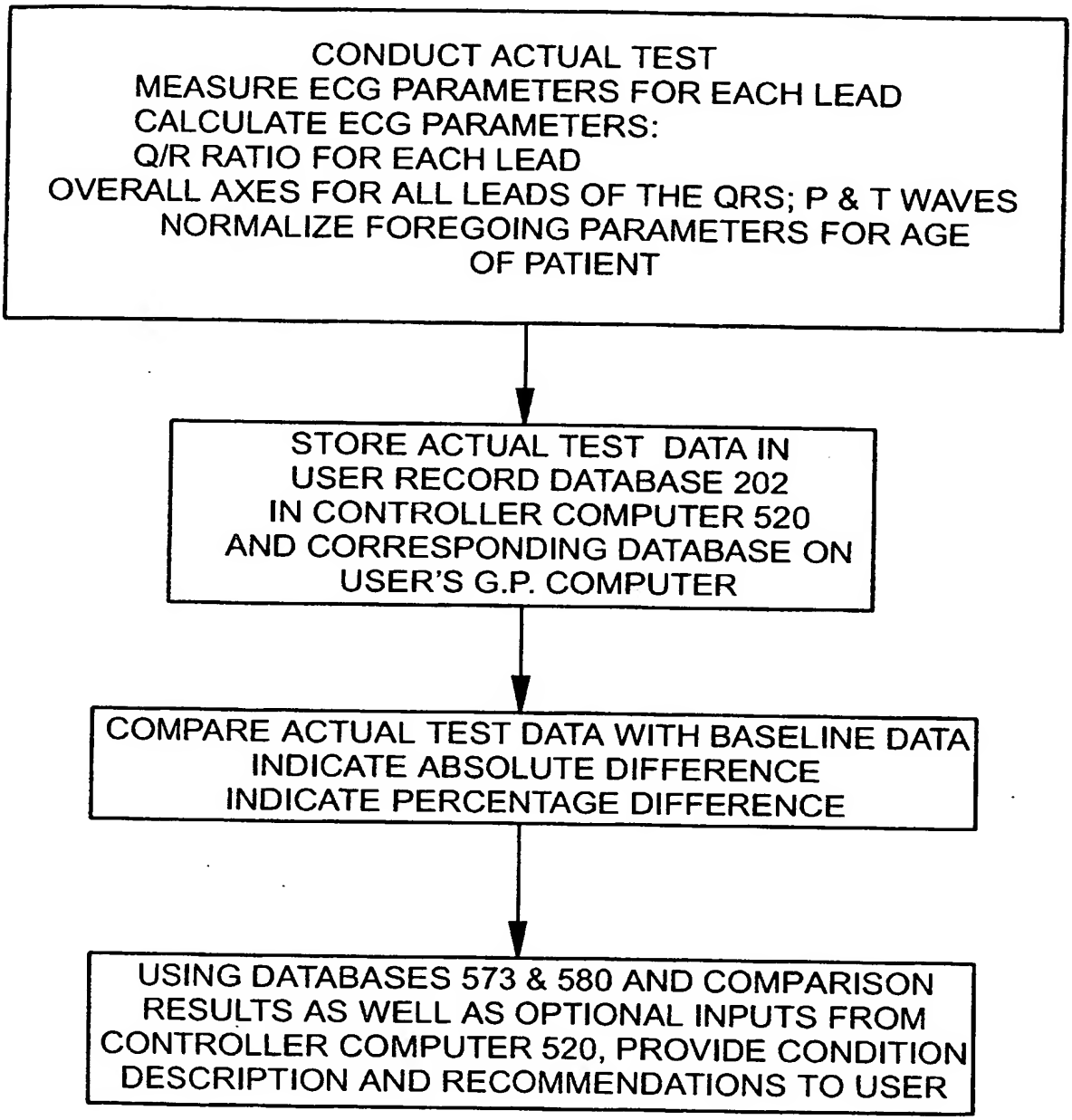

Fig. 7c(2)

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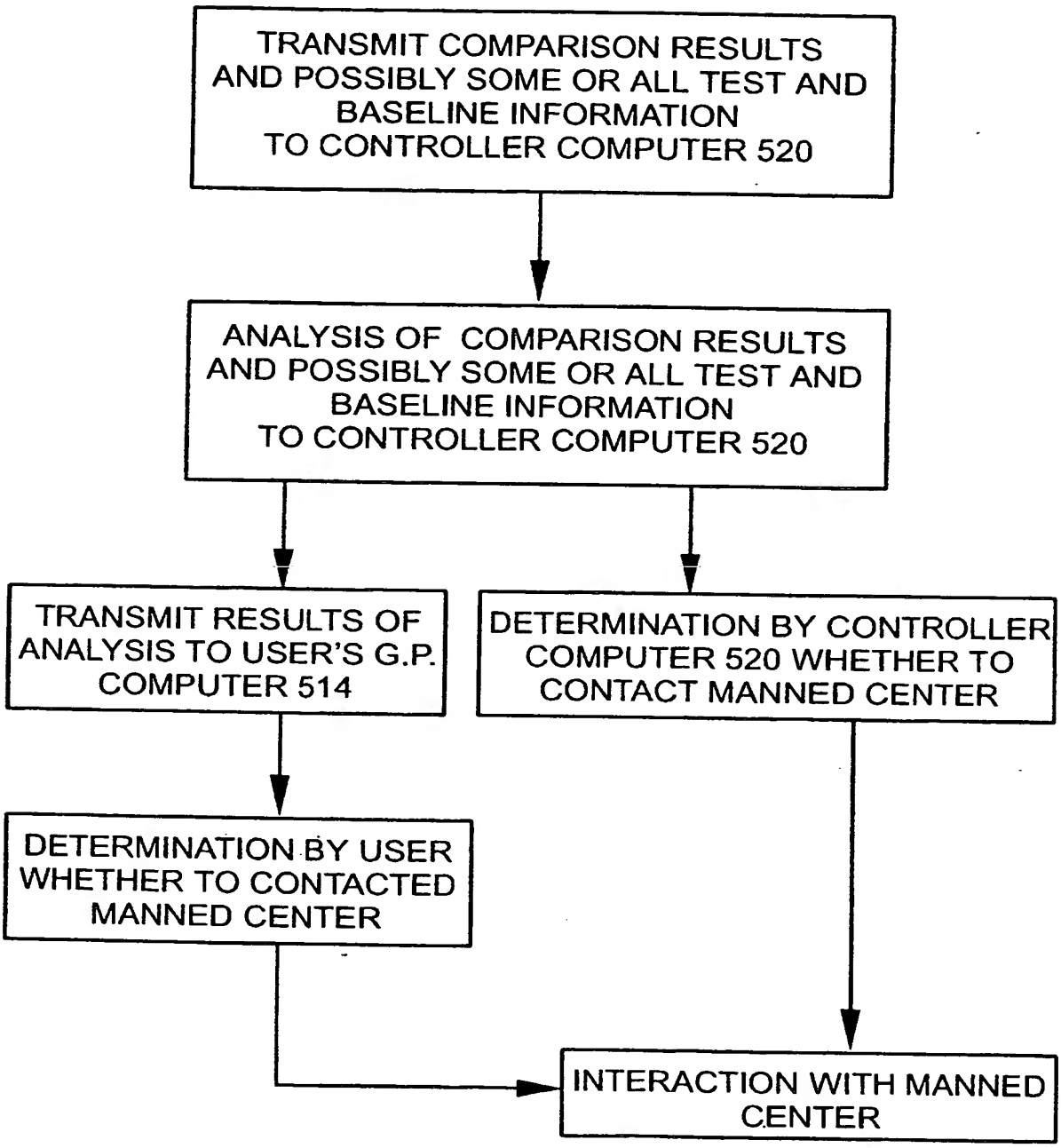

Fig. 7c(3)

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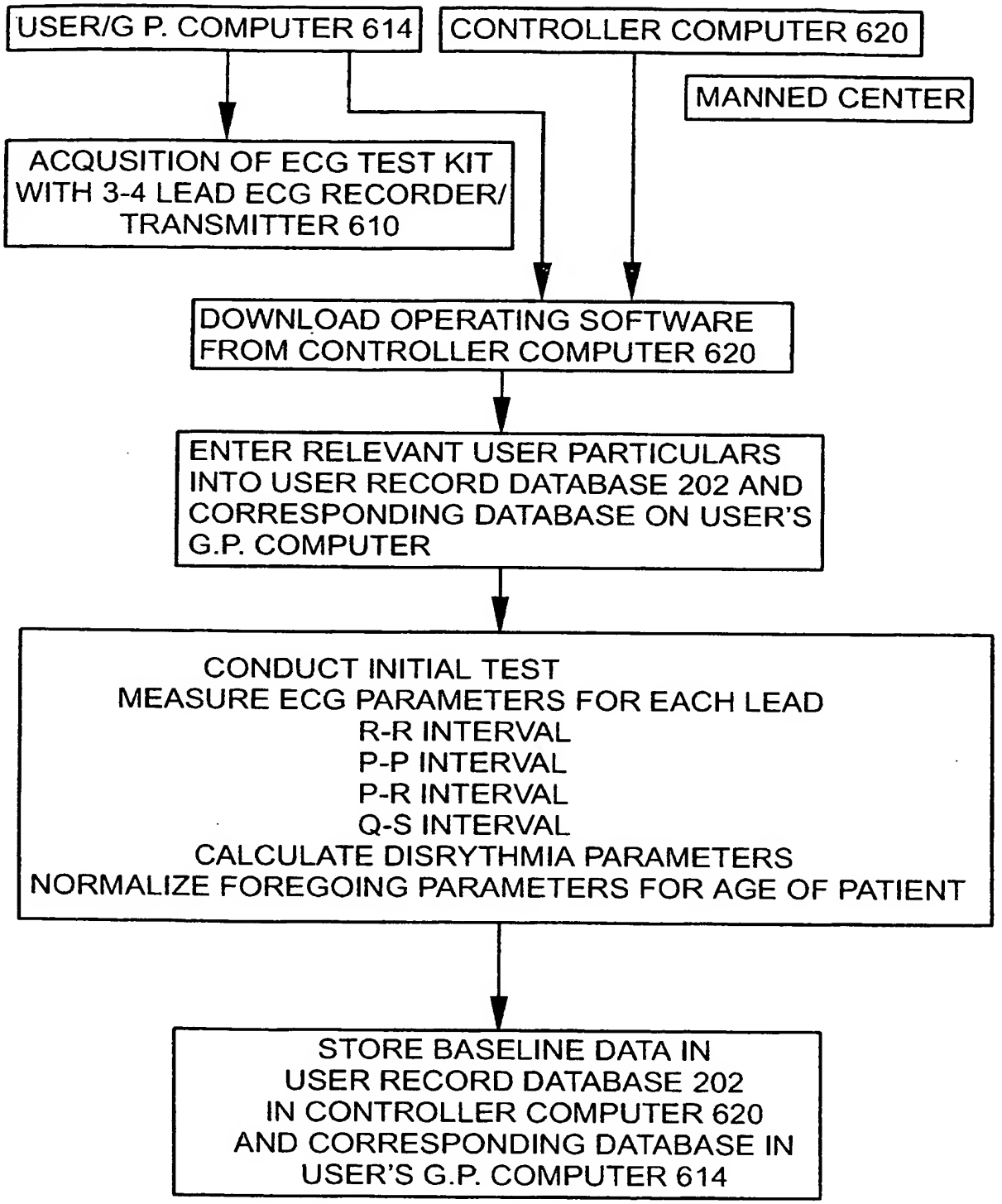

Fig. 7d(1)

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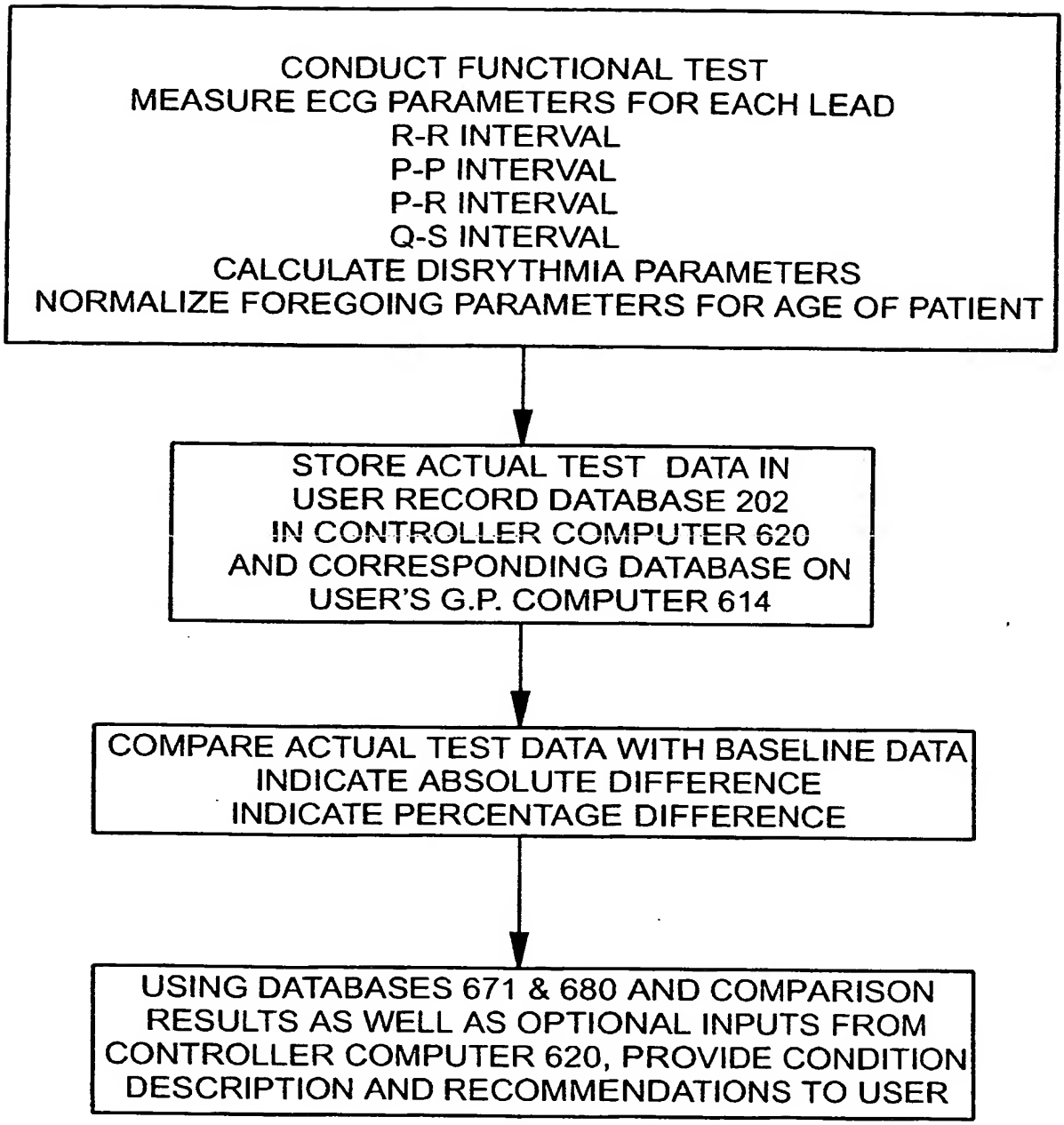

Fig. 7d(2)

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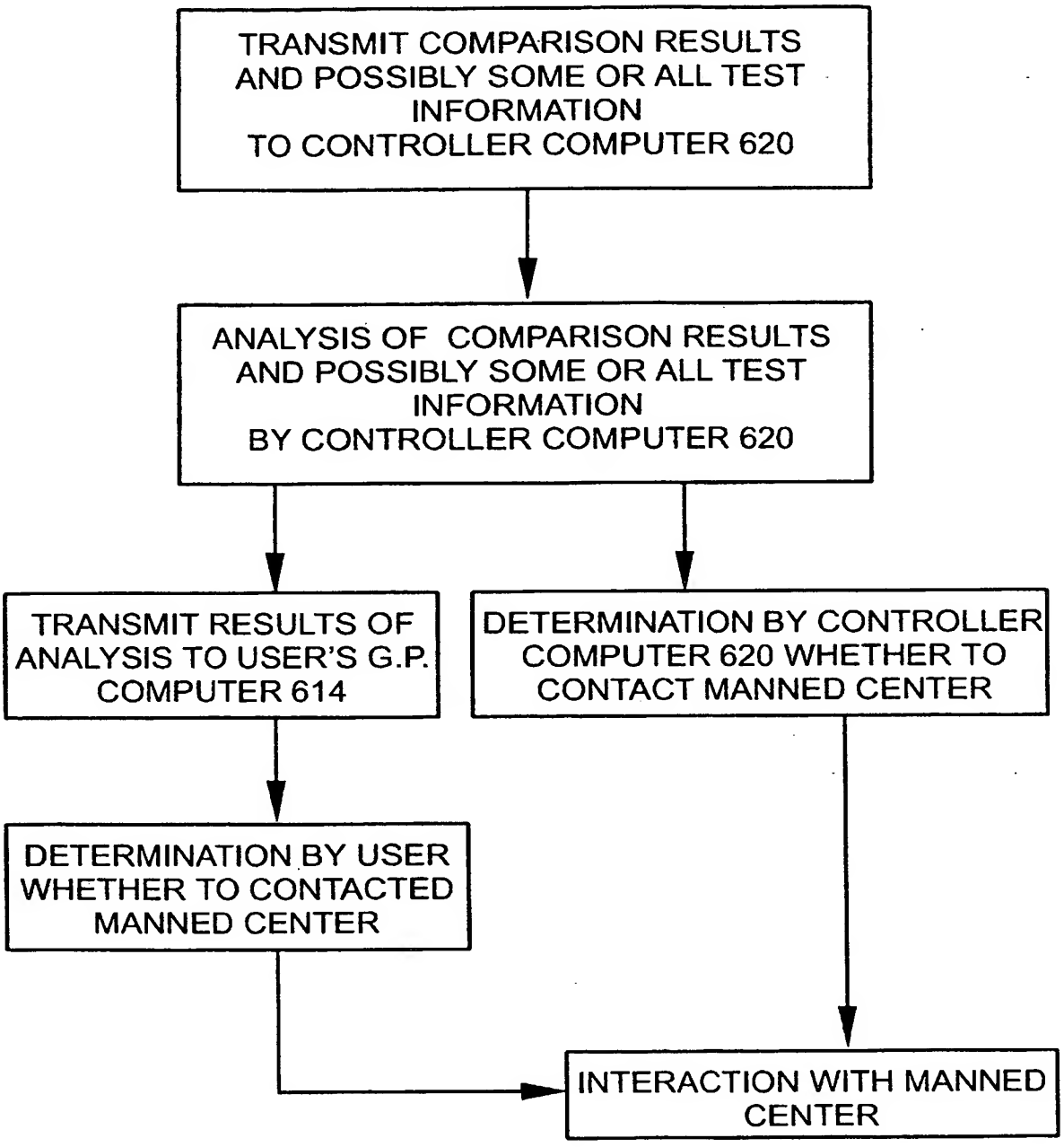

Fig. 7d(3)

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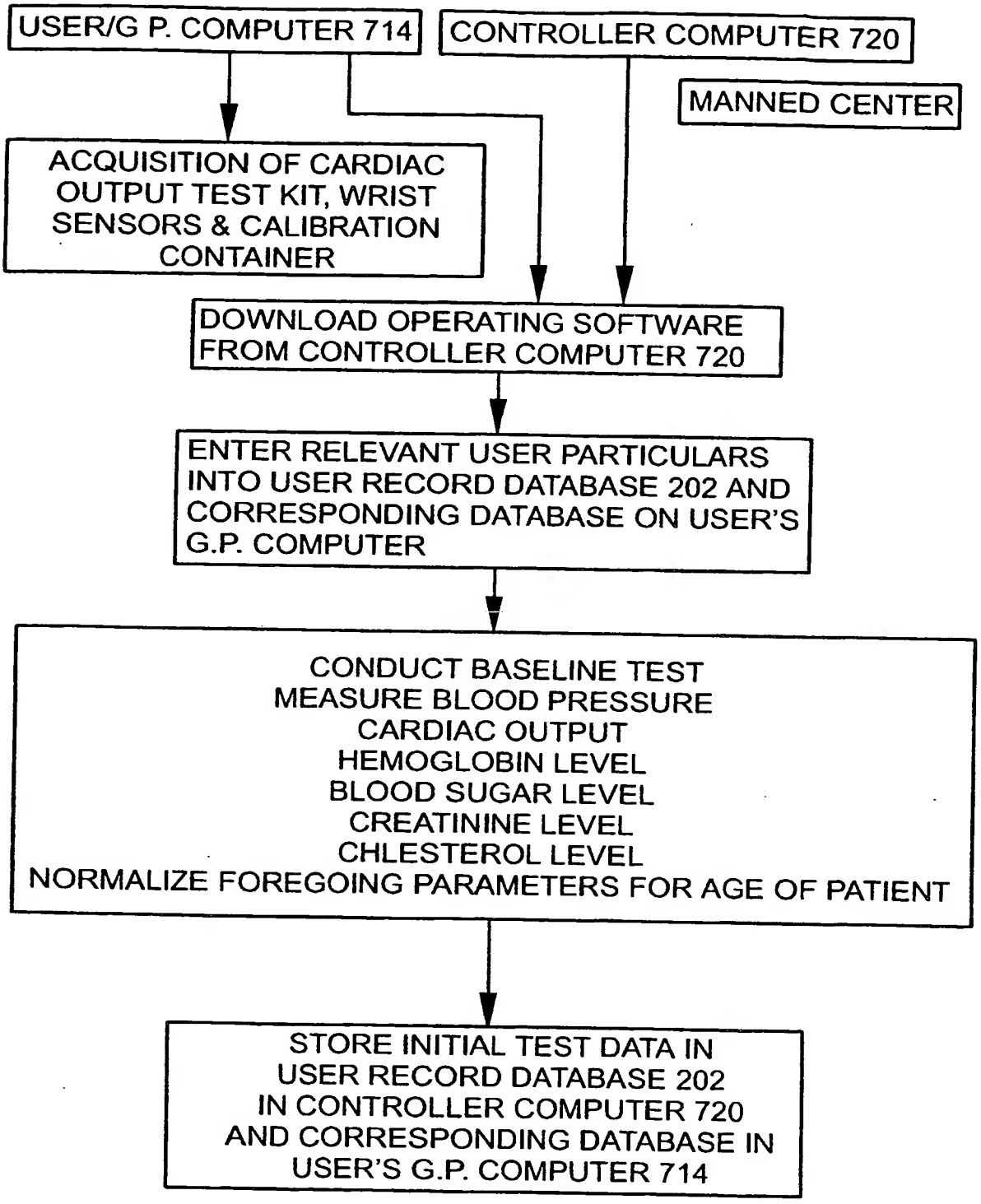

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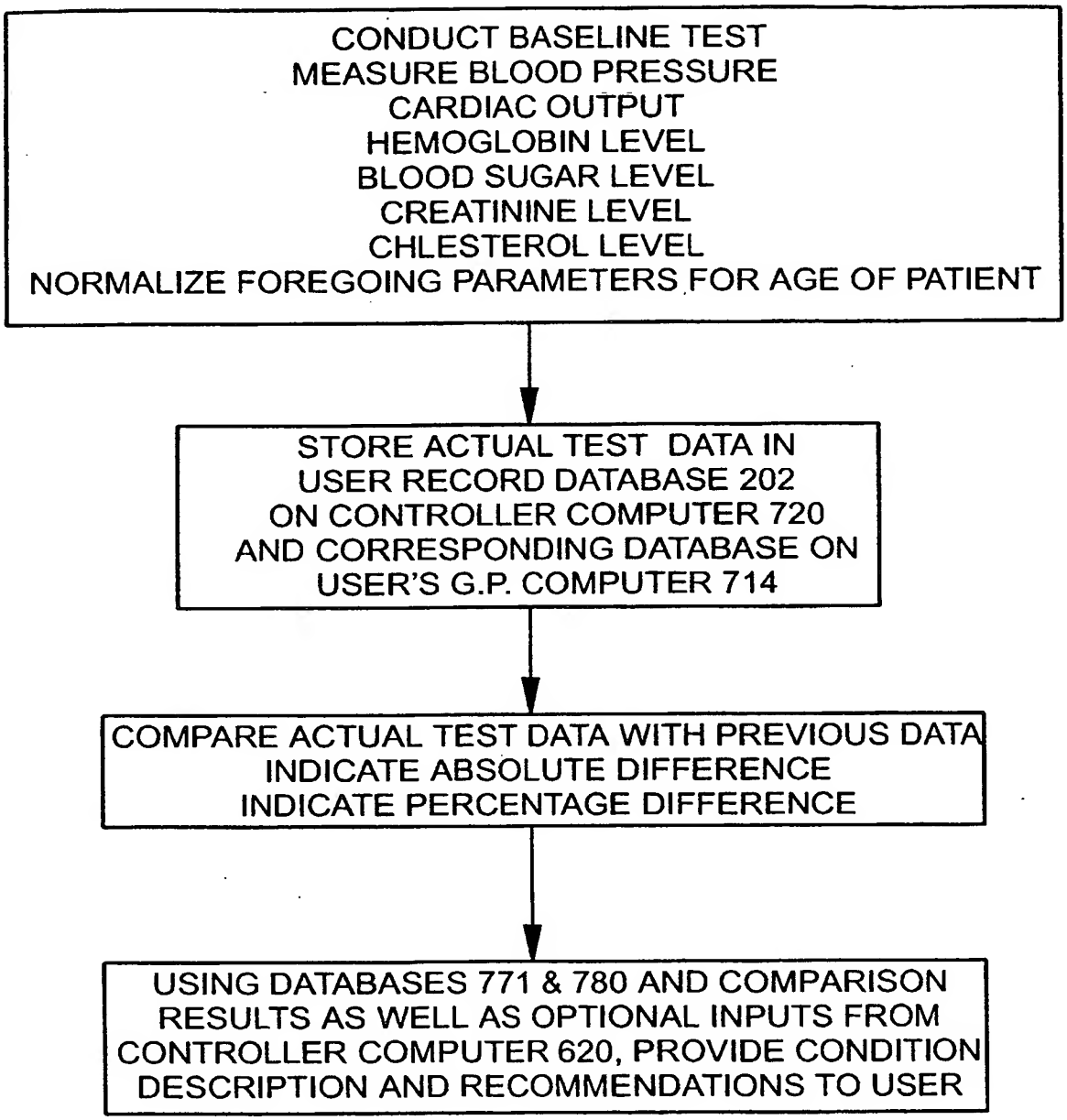

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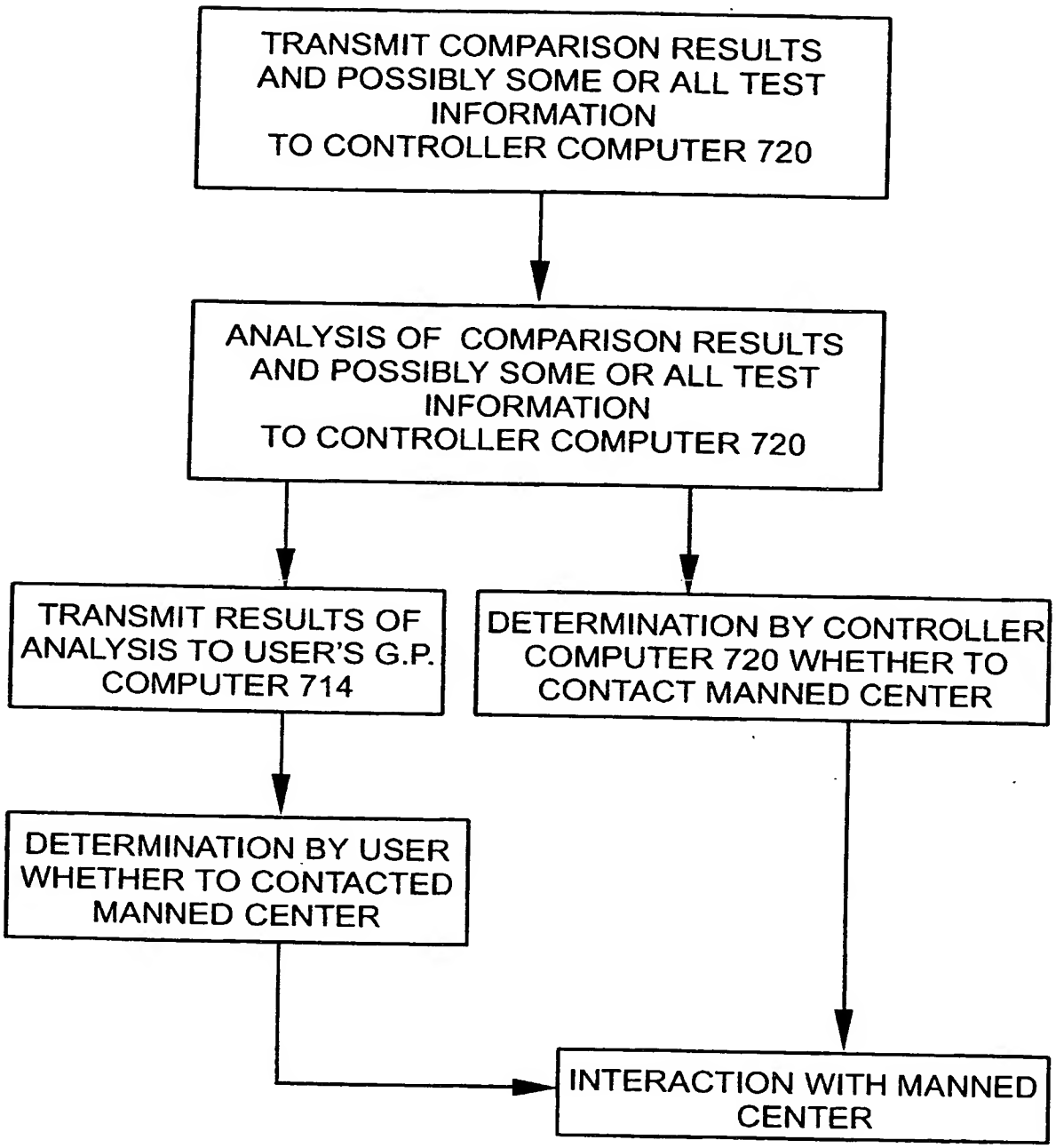

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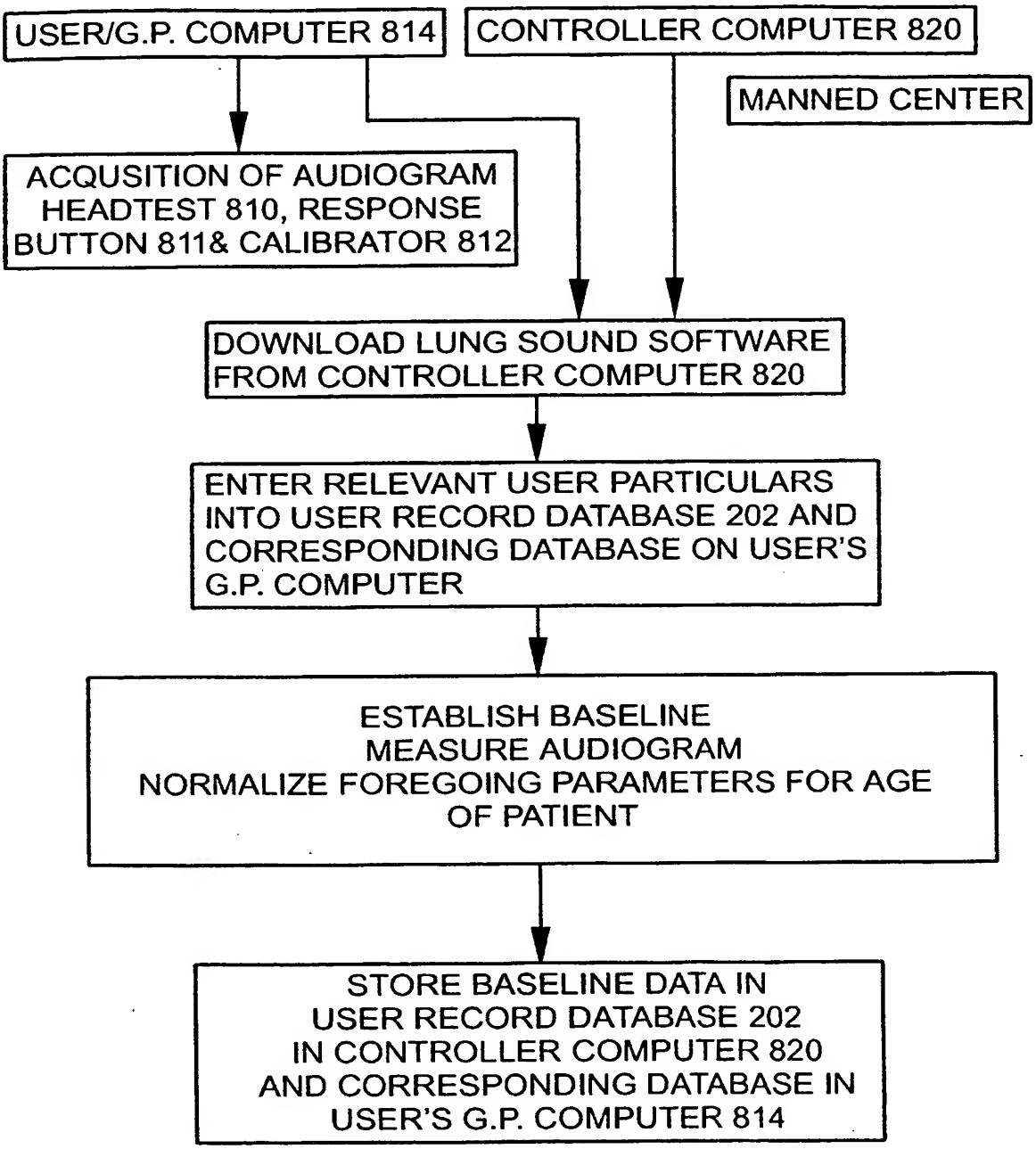

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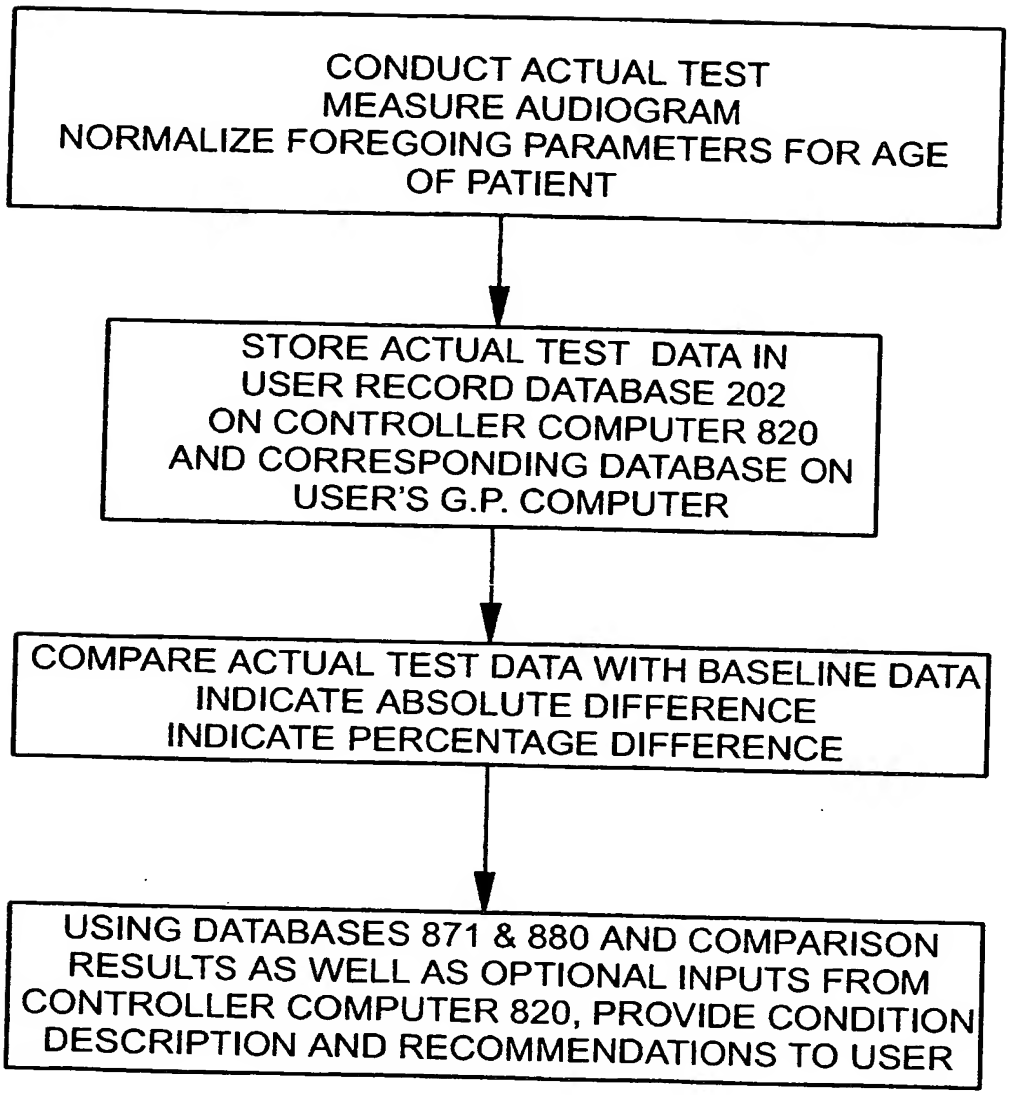

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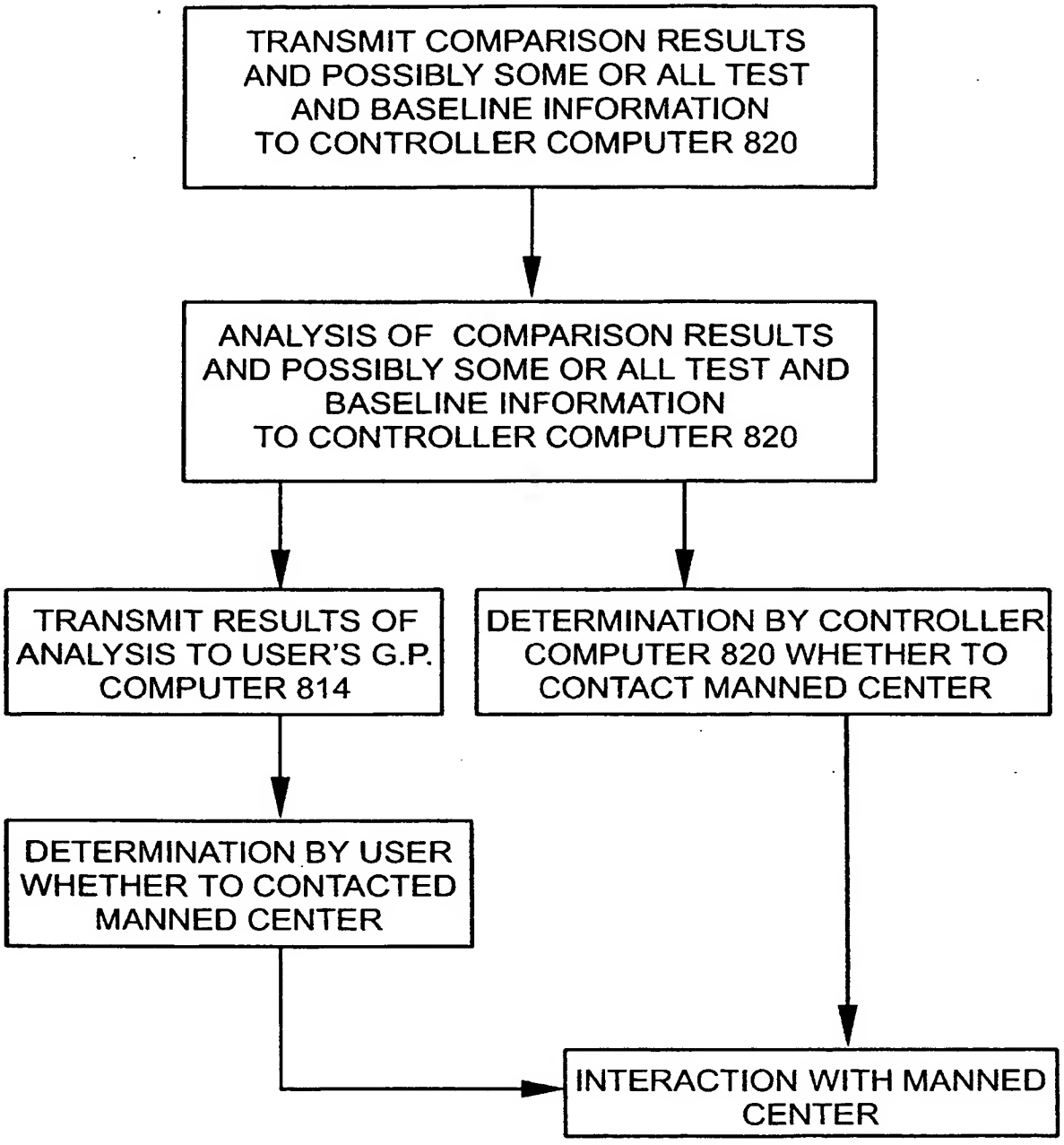

Fig. 7f(3)

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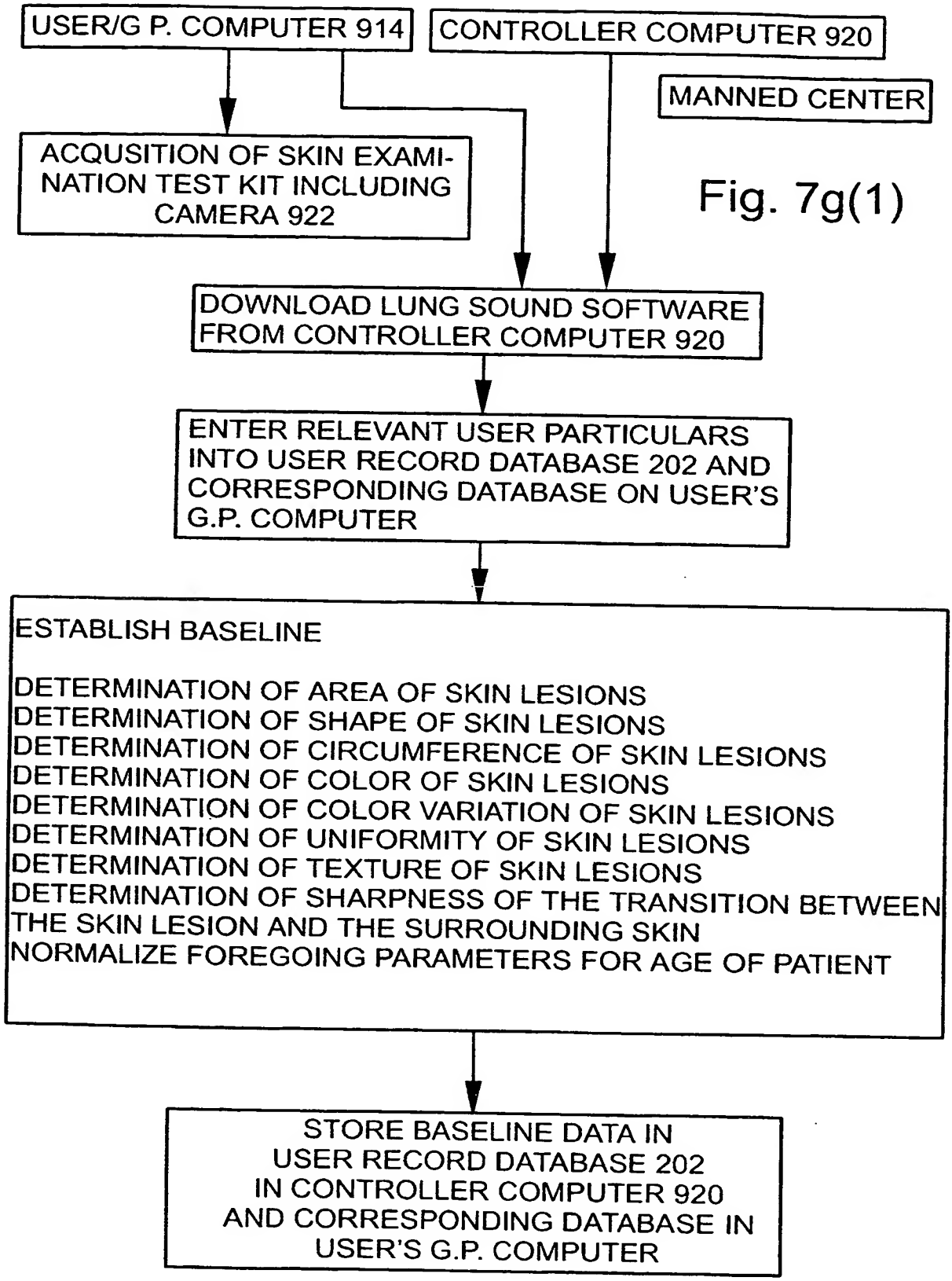

Fig. 7g(1)

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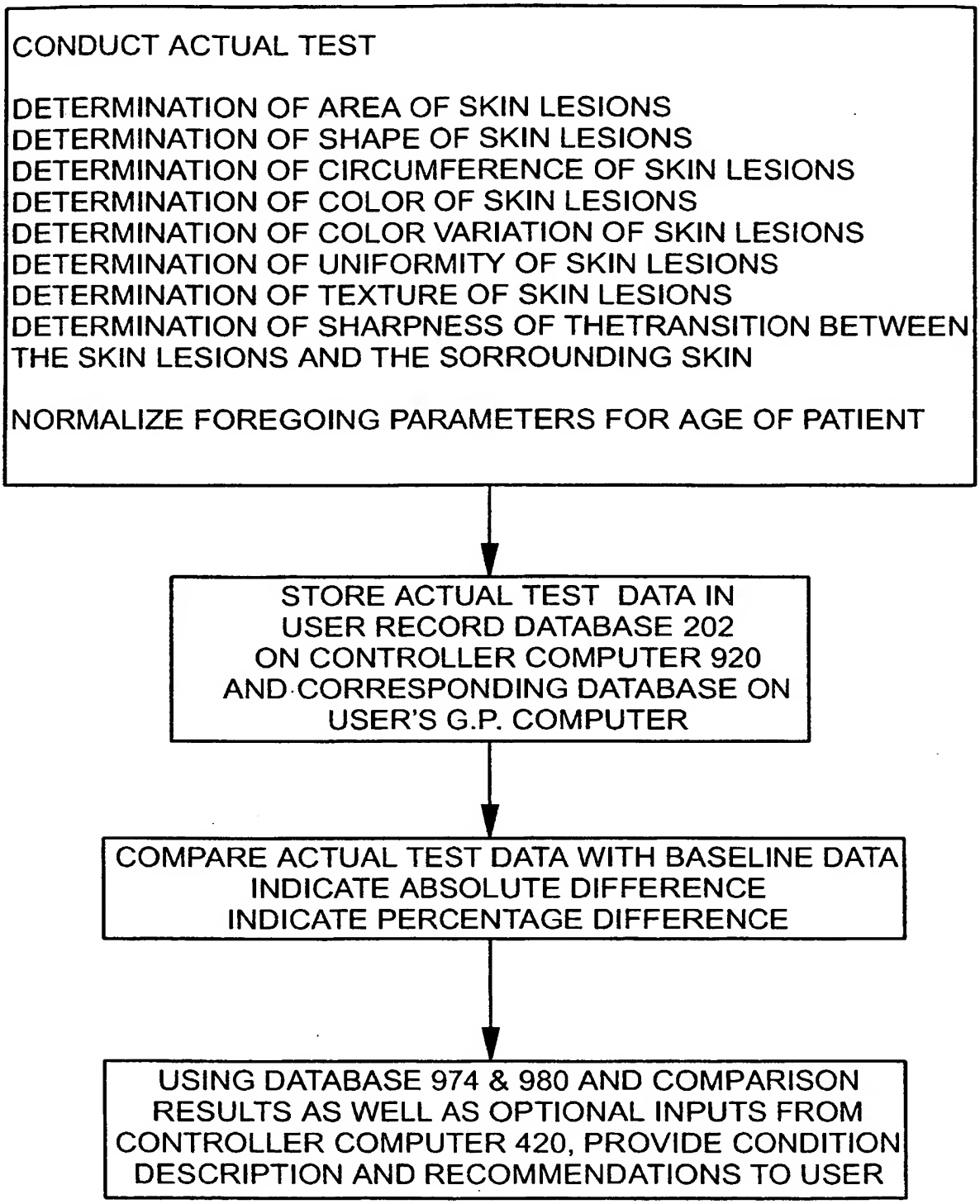

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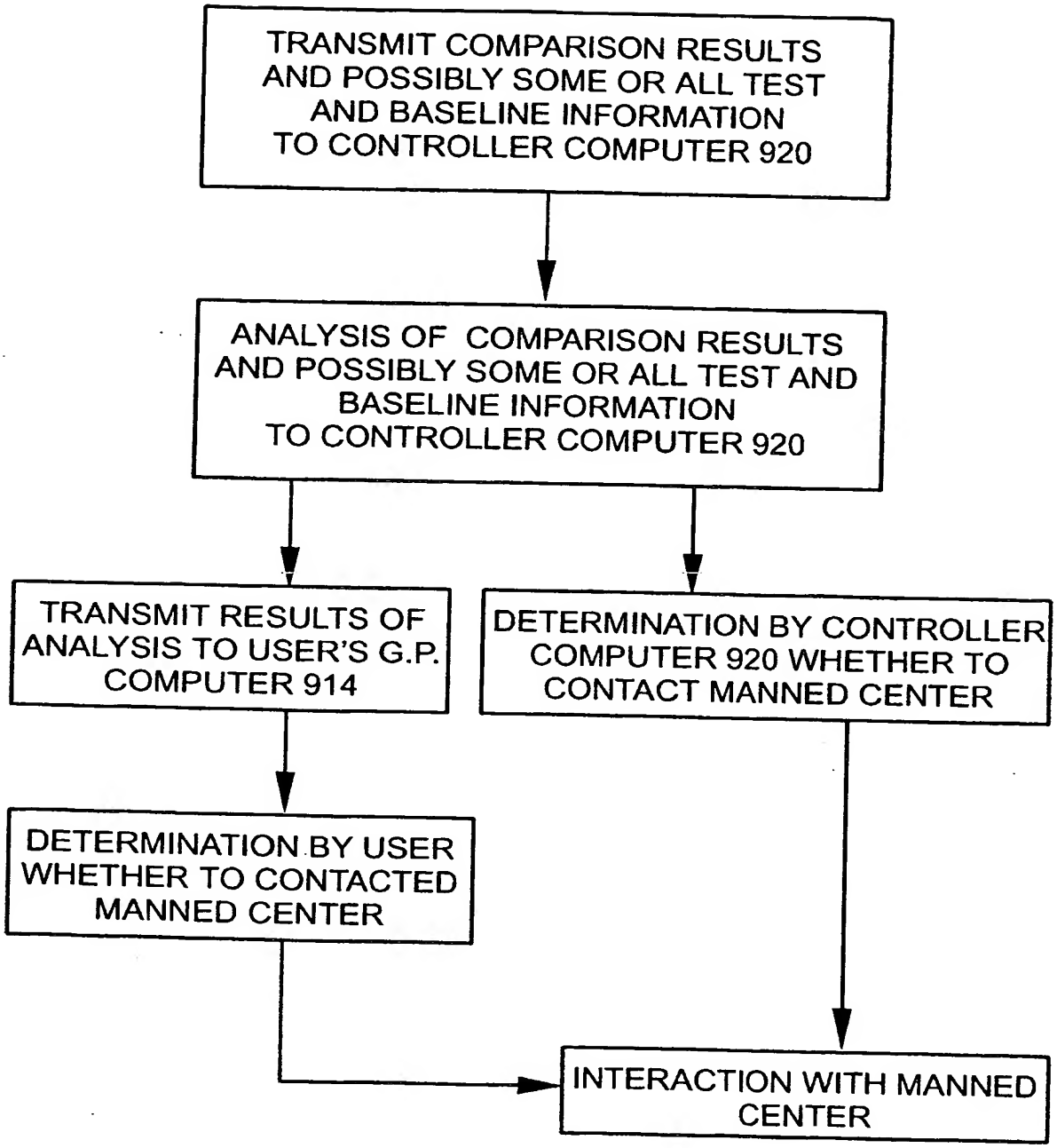

Fig. 7g(3)

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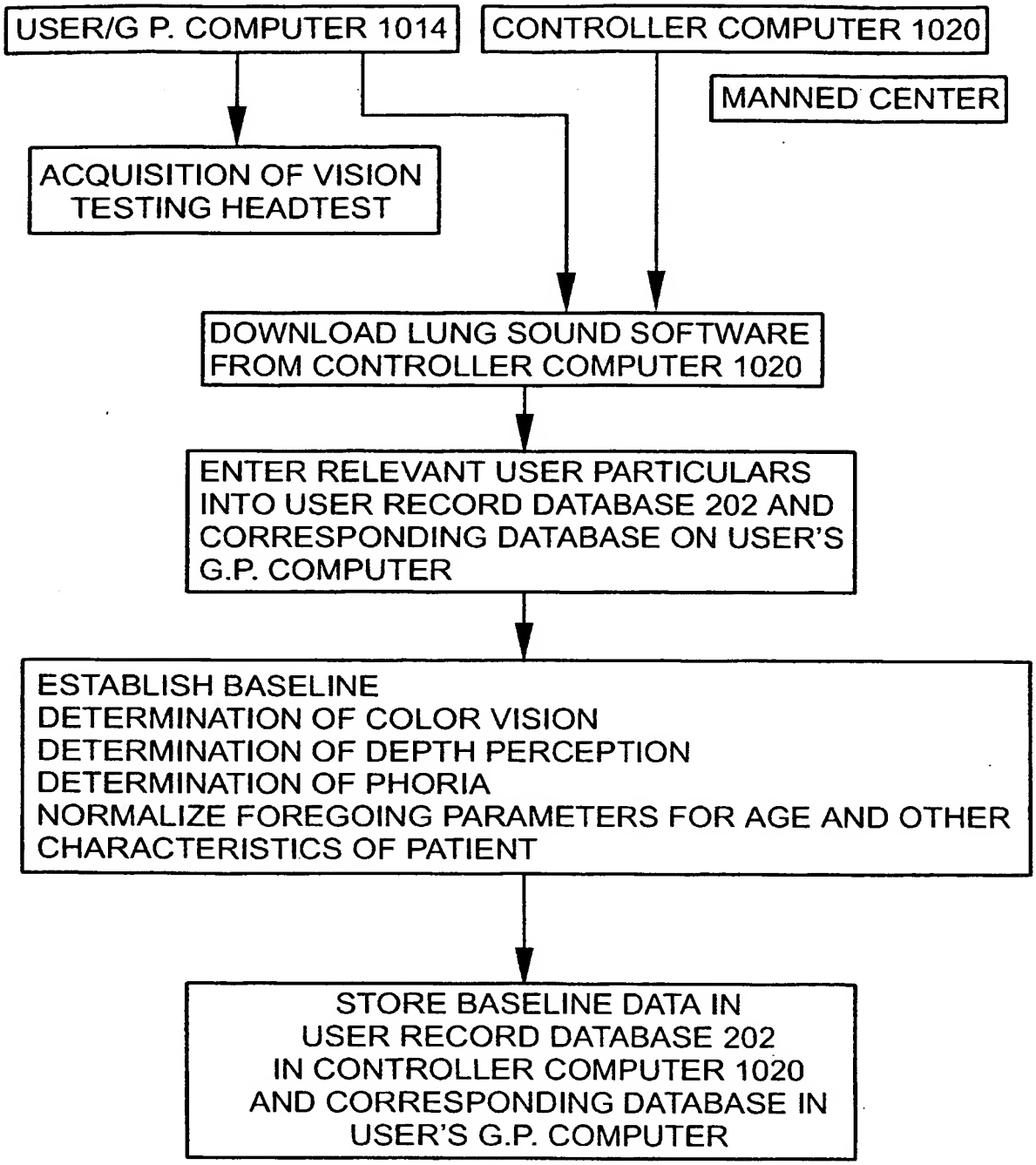

Fig. 7h(1)

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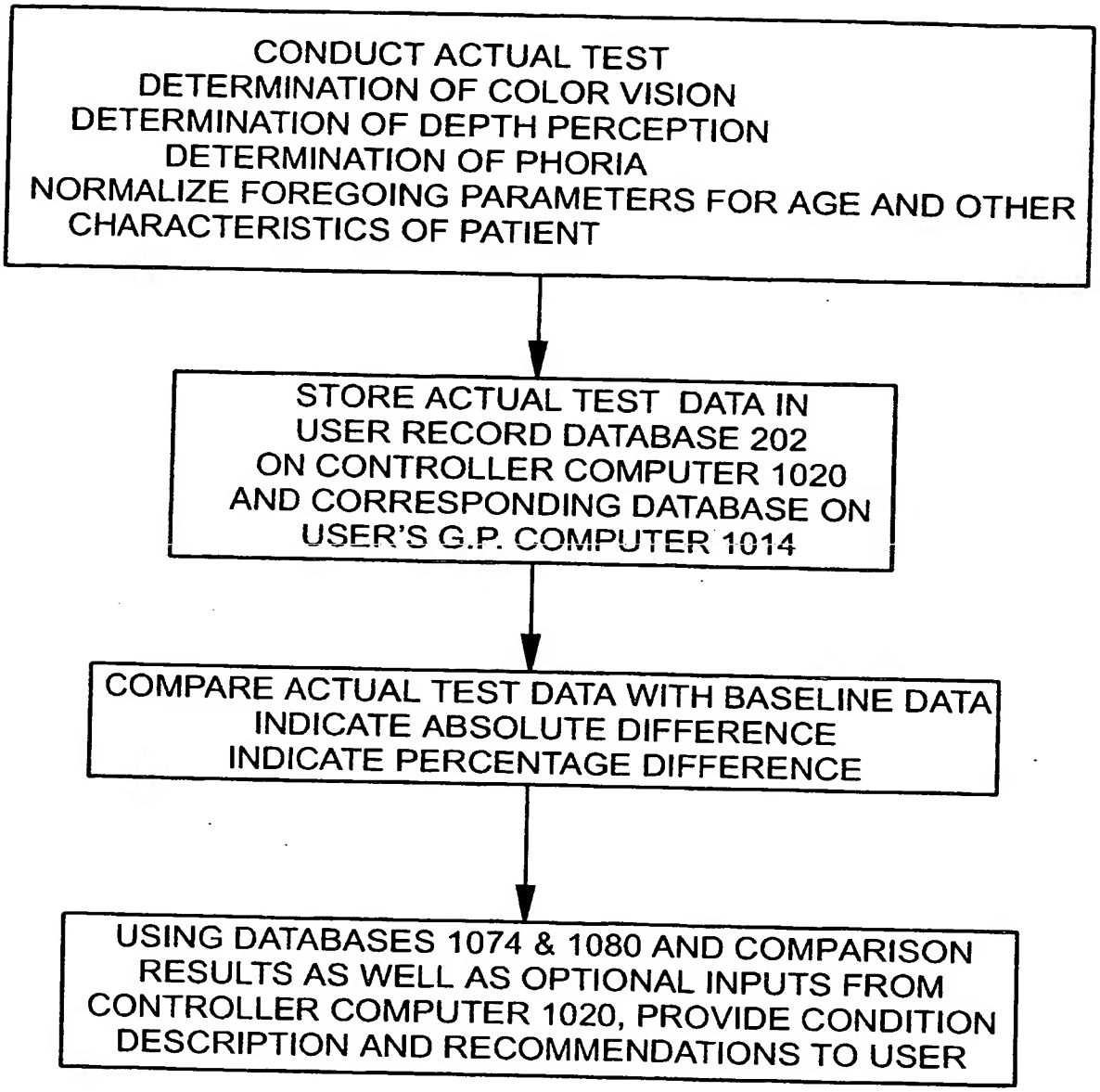

Fig. 7h(2)

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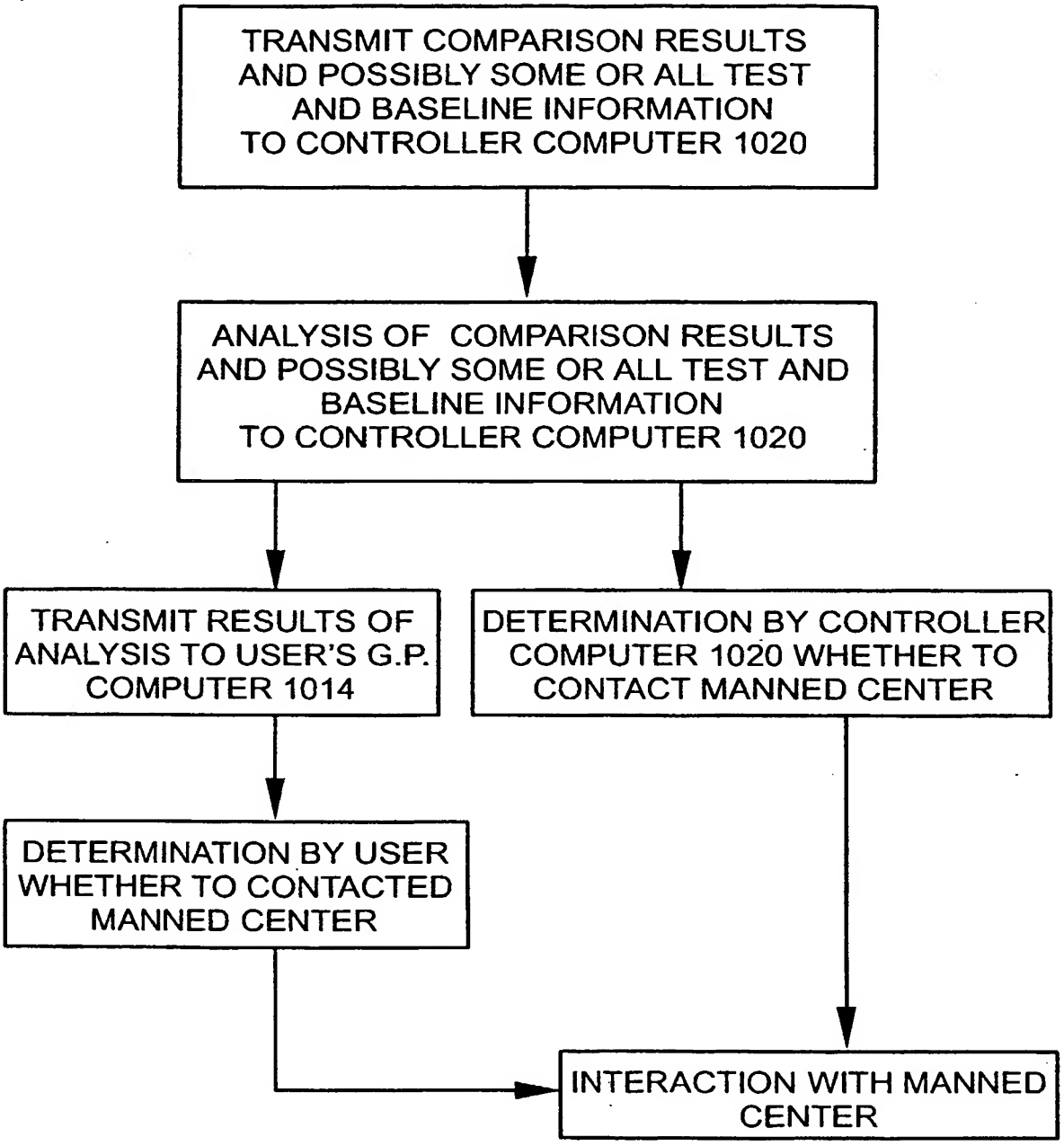


Fig. 7h(3)

OCID: <WO___0130231A2_I_>

DOCID: <WO__0130231A2_1_>

PARAMETER	PREDICTED	BASE LINE DATE:	CURRENT EXAM DATE:	DIFFERENCE [C-B]	RATIO C/B
BREATHING RATE	18	17	25	8	147%
INHALATION/ EXHALITION DURATION RATIO	0.7	0.68	0.4	0.28	58%
WHEEZING PERCENTAGE DURING INHALATION	0	0	5%	5%	- -
DURING EXHALATION	0	3%	25%	22%	- -

A	B	C	D
C/B<15%	15%<C/B<30%	30%<C/B<40%	C/B>40%
WEIGHTING=0	WEIGHTING=1	WEIGHTING=2	WEIGHTING=4

TOTAL=9

HIGHLY SIGNIFICANT CHANGE IN LUNG SOUND/OBTAIN EMERGENCY TREATMENT IMMEDIATELY

Fig. 8a

DOCID: <WO___0130231A2_I_>

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

PARAMETER	MEASURED	BASELINE	PREDICTED	C/B%
FVC	3.50	4.43	4.60	21
FEVI	2.60	3.52	3.83	26
FEF 25-75	2.00	3.81	4.45	48
PF	6.50	10.38	9.13	37

A	B	C	D
20%>(100%-C/B)	20%≤(100%-C/B)<35%	35%≤(100%-C/B)≤50%	(100%-C/B)50%
WEIGHTING=0	WEIGHTING=2	WEIGHTING=4	WEIGHTING=9

TOTAL=12

HIGHLY SIGNIFICANT CHANGE IN LUNG FUNCTIONS/OBTAIN EMERGENCY TREATMENT IMMEDIATELY

Fig. 8b

SUBSTITUTE SHEET (RULE 26)

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

PARAMETER	NORMAL LIMITS	BASELINE	CURRENT	DIFFERENCE	100%-C/B	W.N.L
HEART RATE	50-85	80	100	20	25	NO
P-R INTERVAL	0.1-0.2 MSEC	0.12	0.16	0.04	33	YES
Q-S INTERVAL	0.08-0.12 MSEC	0.1	0.1	0	0	YES
QRS AXIS	20°-70°	60°	80°	20°	25	NO
T AXIS	30°-90°	60°	120°	60°	100	NO
S-T SEGMENT HEIGHT	2 MM	+ 1.5 MM	- 1.0 MM	1.5 MM	- -	NO-

A	B	C	D
20%>C/B	20%≤C/B<30%	C/B>30%	C/B NORMAL LIMITS
WEIGHTING=0	WEIGHTING=2	WEIGHTING=4	WEIGHTING=6

TOTAL=30

HIGHLY SIGNIFICANT CHANGE IN ELECTRO-CARDIOGRAM/OBTAIN EMERGENCY TREATMENT IMMEDIATELY

Fig. 8c

OCID: <WO___0130231A2_I_>

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

PARAMETER	NORMAL LIMITS	BASELINE	CURRENT	DIFFERENCE	W.N.L
HEART RATE	50-85 PER MIN.	80	80	0	YES
R-R INTERVAL	300-800 MSEC.	450 MSEC.	450 MSEC.	0	YES
	UP TO 1 PMB PER MIN.	NO PMB	1 PMB PER MIN.	1 PER MIN.	
P-P INTERVAL	300-800 MSEC.	450 MSEC.	450 MSEC.	0	YES
	UP TO 1 PMB PER MIN.	0	1 PMB	1 PER MIN.	
Q-T INTERVAL	80-120 MSEC.	100 MSEC.	250 MSEC.	0	YES
	UP TO 1 PMB PER MIN.	0	1 PER MIN.	1 PER MIN.	

A	B	C	D
WEIGHTING=0	WEIGHTING=4	WEIGHTING=9	WEIGHTING=4

TOTAL=17

SIGNIFICANT CHANGE IN ELECTRO-CARDIOGRAM/ELECTRO-CARDIOGRAM DATA BEING TRANSFERRED TO CONTROLLER AND/OR MANNED CENTER FOR EVALUATION OBTAIN EMERGENCY TREATMENT IMMEDIATELY

Fig. 8d

SUBSTITUTE SHEET (RULE 26)

DOCID: <WO__0130231A2_I_>

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

PARAMETER	NORMAL LIMITS	BASELINE	CURRENT	100%-C/B	W.N.L
HEART RATE	50-85	80	80	0	YES
BLOOD PRESSURE	100/60 TO 140/60 mmHg	120/80	120/80	0	YES
CARDIAC OUTPUT	4.5-6 LIT./MIN.	4.5	4.05	10%	NO

A	B	C	ANY PARAMETER > NORMAL LIMITS
WEIGHTING=0	WEIGHTING=2	WEIGHTING=4	WEIGHTING=8

TOTAL=8
SLIGHT CHANGE IN CARDIAC PARAMETERS/CONTACT PHYSICIAN/REPEAT TEST

Fig. 8e

SUBSTITUTE SHEET (RULE 26)

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

PARAMETER	NORMAL LIMITS	BASELINE	CURRENT	C/B	W.N.L
AVERAGE 500-3000 Hz	0-20dB	15dB	20dB	33	YES
4000-8000 Hz	0-25dB	20dB	40dB	100	NO
SLOPE	UPTO 25°	25°	50°	100%	NO

A	B	C
WEIGHTING=0	WEIGHTING=2	WEIGHTING=6

TOTAL=24
SIGNIFICANT CHANGE IN AUDIOGRAM/CONSULT PHYSICIAN

Fig. 8f

SUBSTITUTE SHEET (RULE 26)

IOCID: <WO__0130231A2_I_>

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

PARAMETER	NORMAL LIMITS	BASELINE	CURRENT	C/B%	W.N.L
AREA	--	1.2 CM^2	1.6 CM^2	33	--
CIRCUM-FERENCE	--	2.5 CM	3.75 CM	50	--
UNIFORMITY	--	UNIFORMITY	PATCHY	--	NO
SHARPNESS OF BORDER	SHARP	SHARP	20% OF BORDER-NOT SHARP	--	NO

A	B	C
WEIGHTING=2	WEIGHTING=4	WEIGHTING=6

TOTAL=20

SIGNIFICANT CHANGE IN SKIN LESIONS/CONSULT PHYSICIAN

Fig. 8g

IOCID: <WO__0130231A2_1_>

PARAMETER	NORMAL LIMITS	BASELINE	CURRENT	DIFFERENCE	W.N.L
VISUAL ACUITY 40 CMS	40 CM / 40 CM	40 CM / 40 CM	40 CM / 40 CM	--	YES
VISUAL ACUITY 600 CMS	6 M / 6 M	6 / 18	6 / 18	--	NO
DEPTH PERCEPTION	100%-70%	80%	60%	20%	YES

DATE 02/08/99 AT 18:27
AGE:37 YEARS HEIGHT: 172 CM
SEX: MALE WEIGHT: 67 KG

A	B	C
WEIGHTING=0	WEIGHTING=8	WEIGHTING=4

TOTAL=4

CHANGE IN VISION FROM PREVIOUS EXAMINATION OR VISION OUTSIDE NORMAL LIMITS/CONTACT VISION PROFESSIONAL/ REPEAT TEST

Fig. 8h

SUBSTITUTE SHEET (RULE 26)

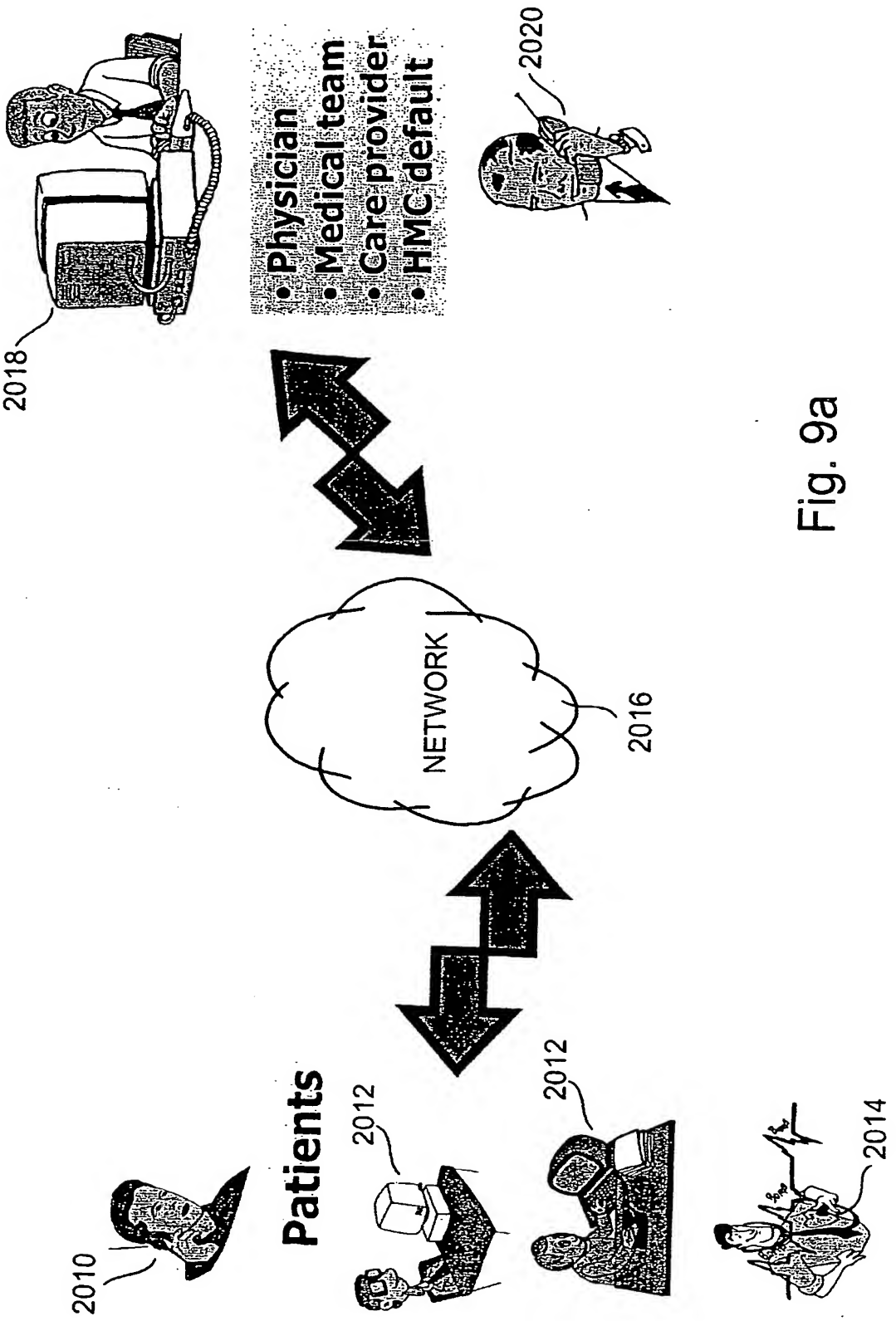


Fig. 9a

DOCID: <WO___0130231A2_I_>

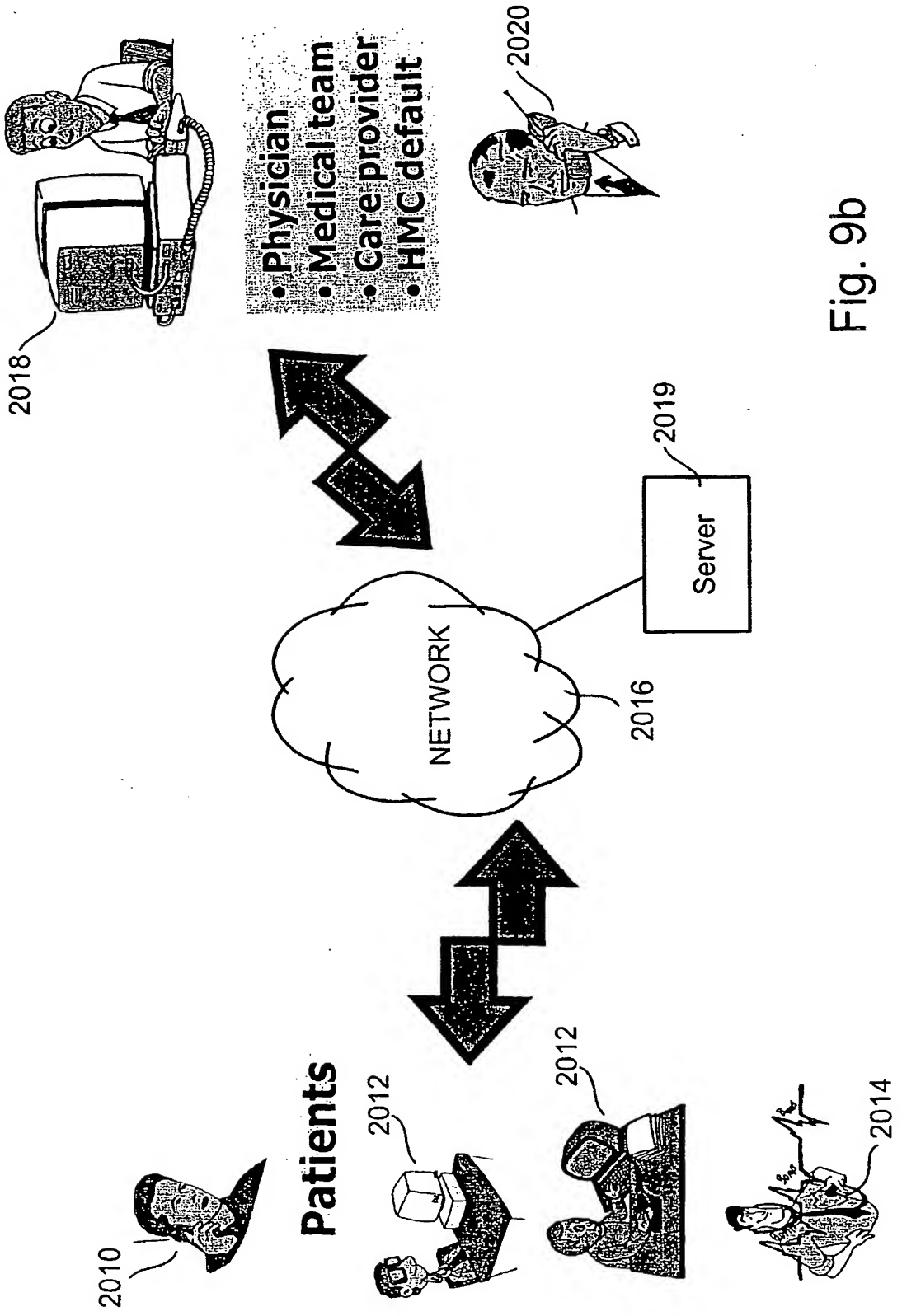


Fig. 9b

SUBSTITUTE SHEET (RULE 26)

)OCID: <WO___0130231A2_I_>

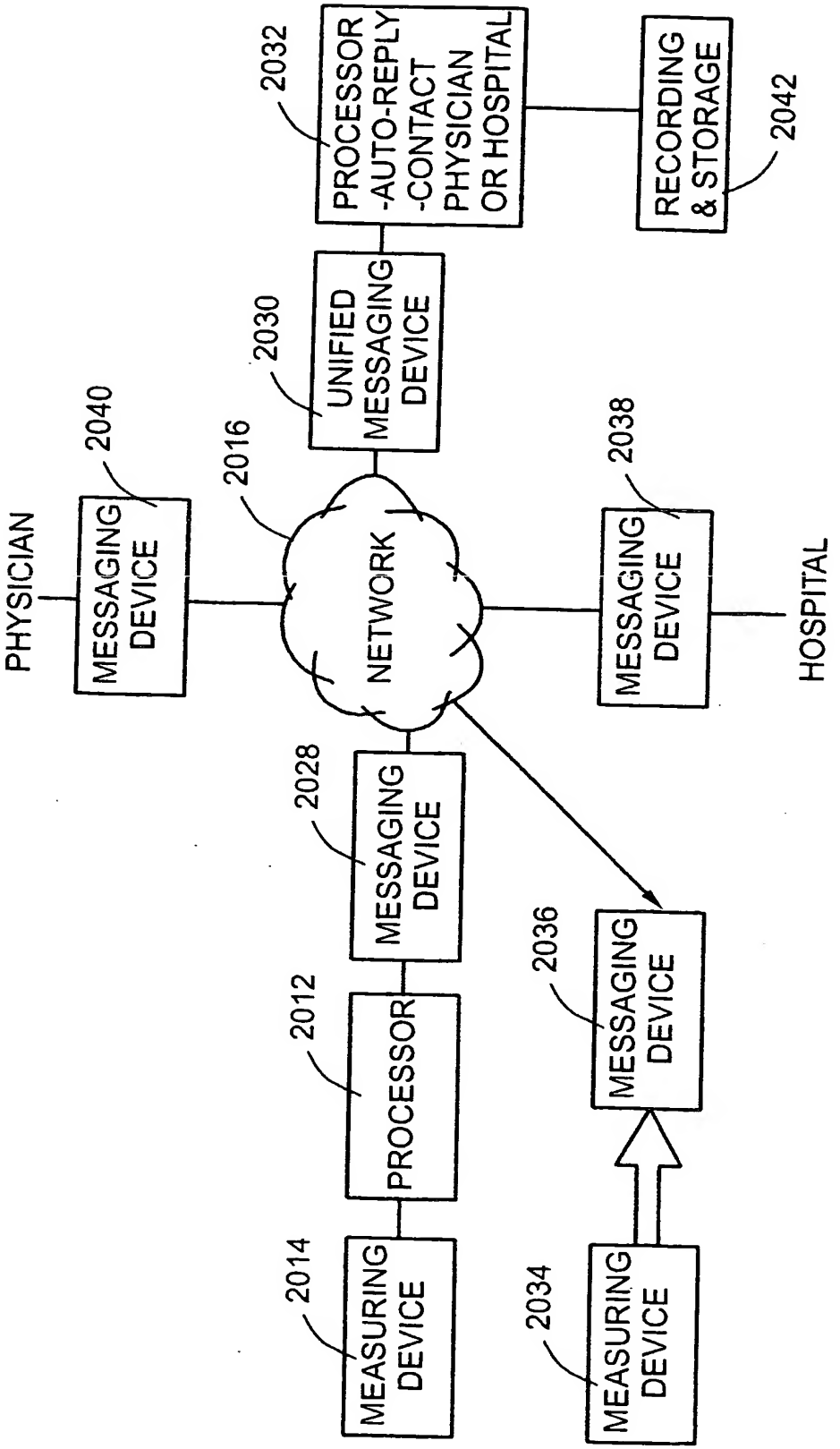


Fig. 10

)OCID: <WO___0130231A2_I_>

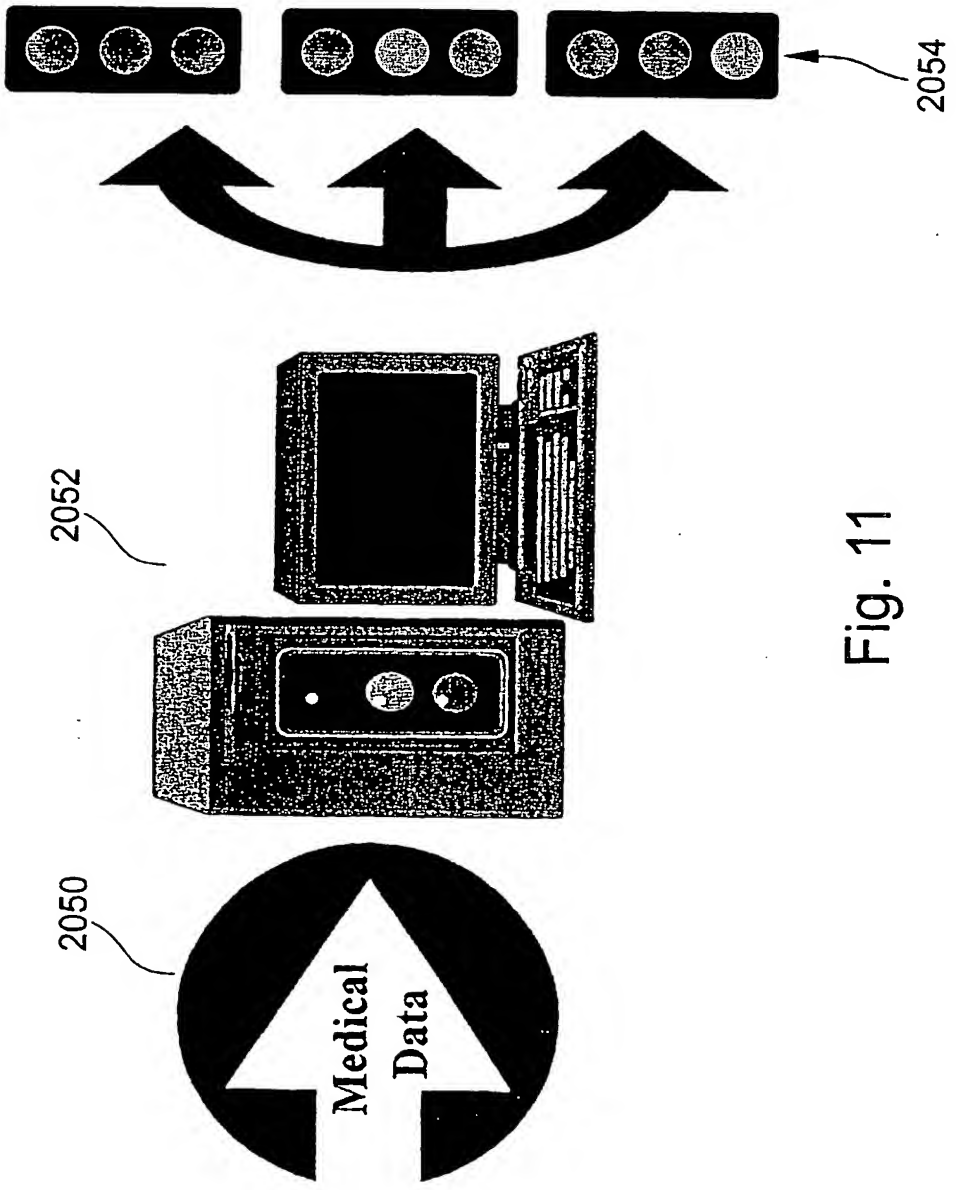


Fig. 11

OCID: <WO___0130231A2_I_>

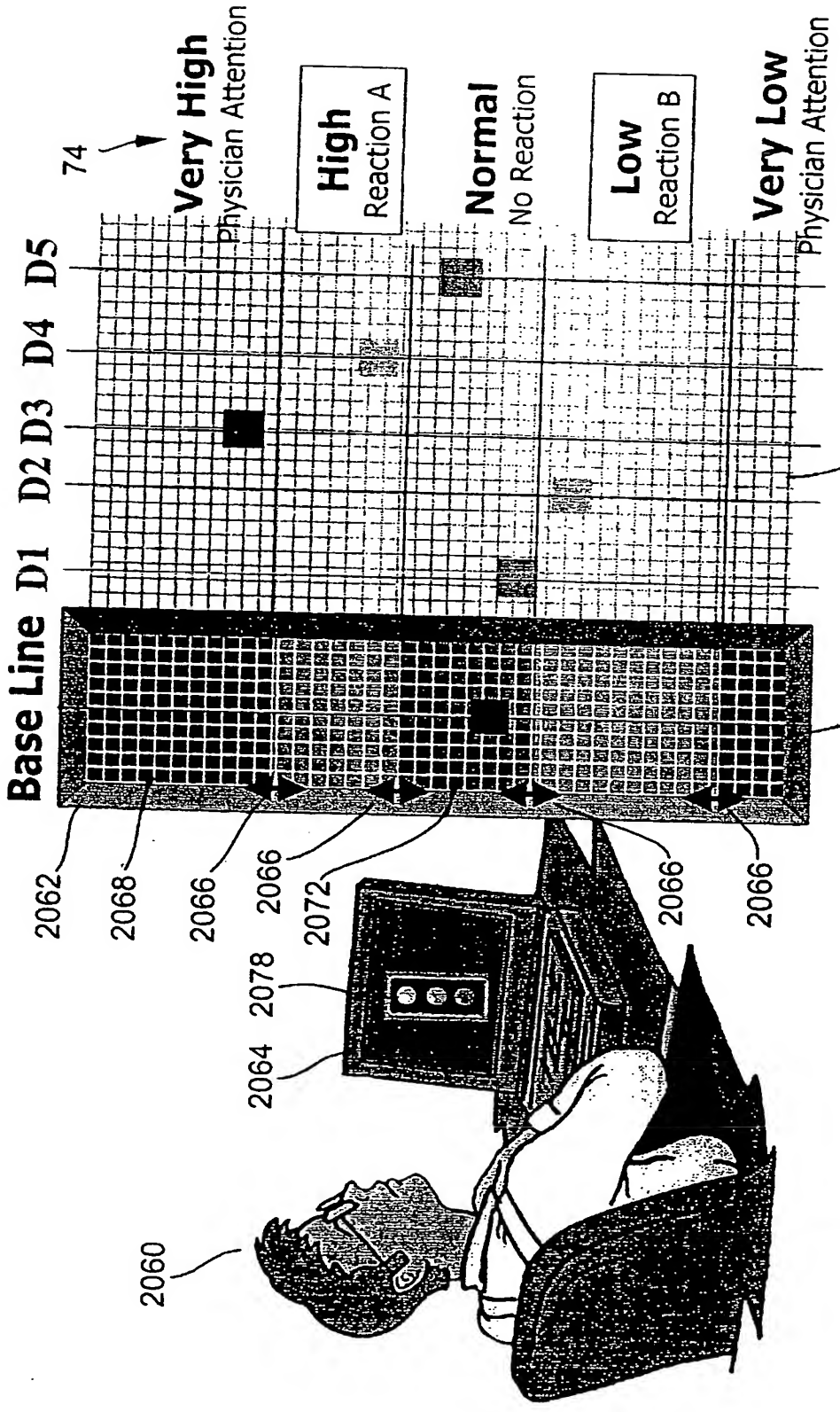
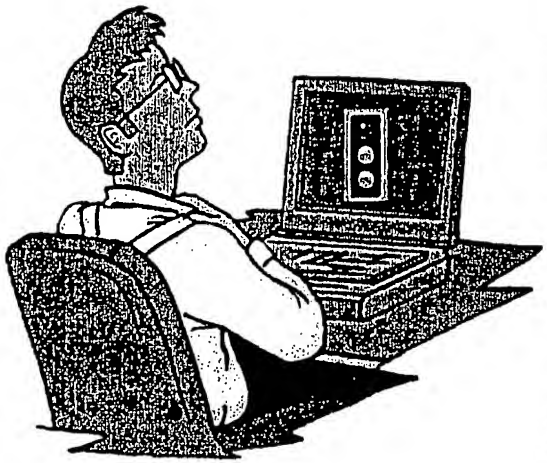


Fig. 12

IOCID: <WO___0130231A2_I_>

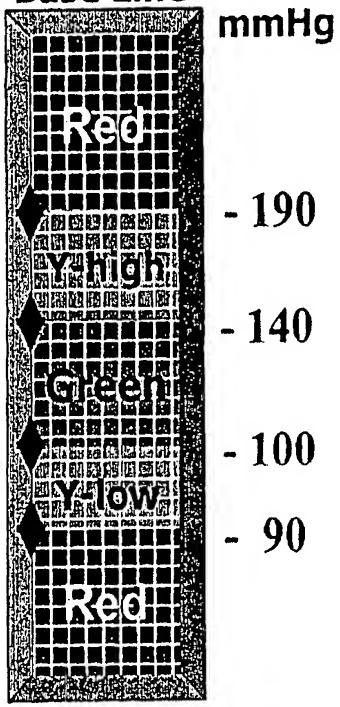
DOCID: <WO__0130231A2_1_>

Systolic blood pressure



Maximum change per test

20%



Recommendation

- Contact your physician.

- Take another_____ Tablet. Repeat B.P. test in two hours.

- Thank you. Repeat test tomorrow.

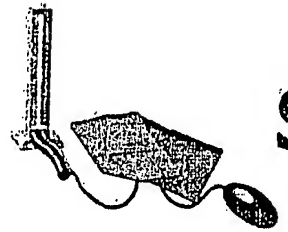
- Stop for today_____. Drink water and repeat B.P. test in two hours.

- Contact your physician. Call an ambulance.

Fig. 13a

SUBSTITUTE SHEET (RULE 26)

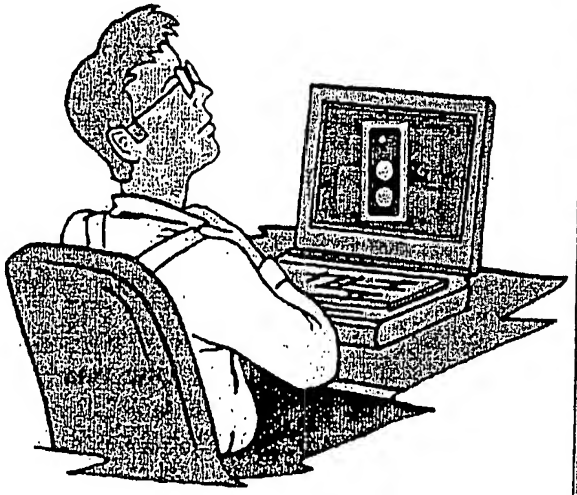
DOCID: <WO___0130231A2_I_>



Systolic blood pressure

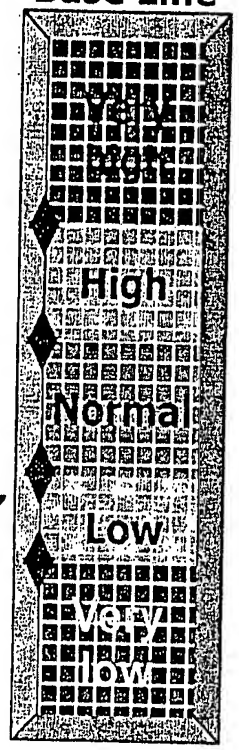
Maximum change between tests

24%



Base Line

mmHg



Recommendation

- Contact your physician.

- Take another_____ Tablet. Repeat B.P. test in two hours.

- Thank you. Repeat test tomorrow.

- Stop for today_____. Drink water and repeat B.P. test in two hours.

- Contact your physician. Call an ambulance.

Fig. 13b

SUBSTITUTE SHEET (RULE 26)

<DOCID: <WO__0130231A2_I_>

Diastolic blood pressure

Maximum change per test

20%

Recommendation

- Contact your physician.

- Take another_____ Tablet.
  Repeat B.P. test in two hours.

- Thank you. Repeat test tomorrow.

- Stop for today_____. Drink water and repeat B.P. test in two hours.

- Contact your physician. Call an ambulance.

Fig. 14a

SUBSTITUTE SHEET (RULE 26)

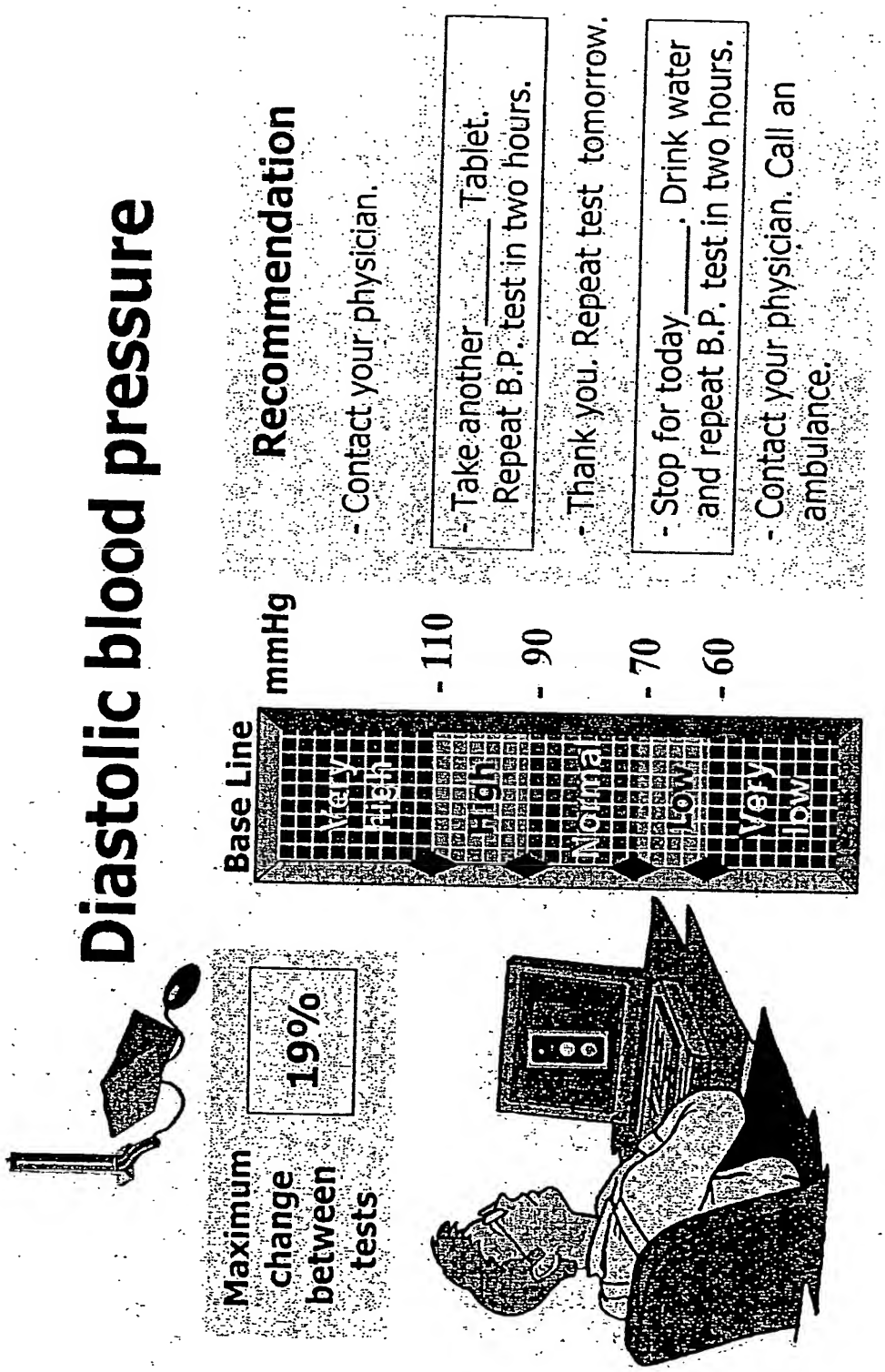


Fig. 14b

XOCID: <WO___0130231A2_I_>

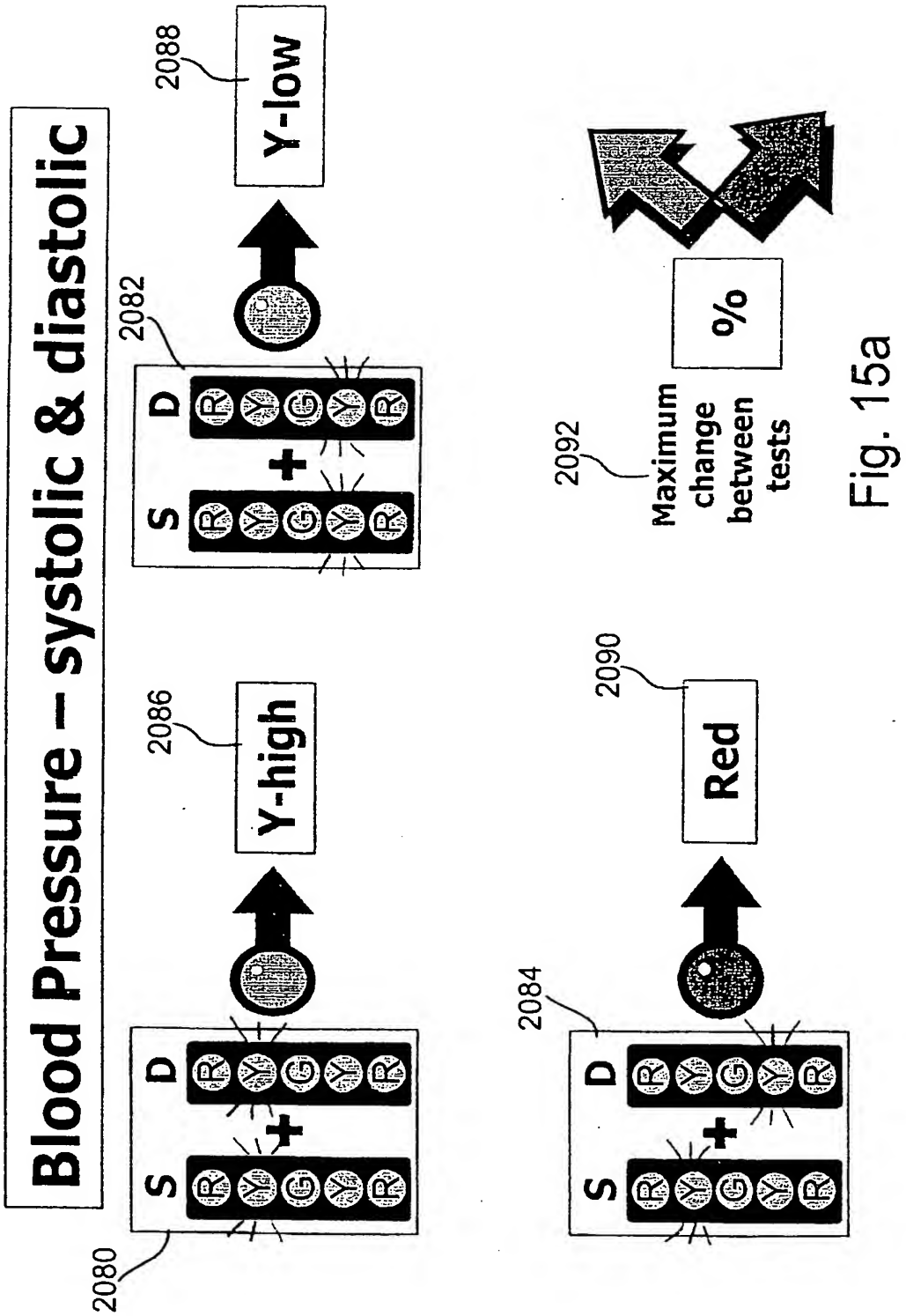


Fig. 15a

)OCID: <WO___0130231A2_I_>

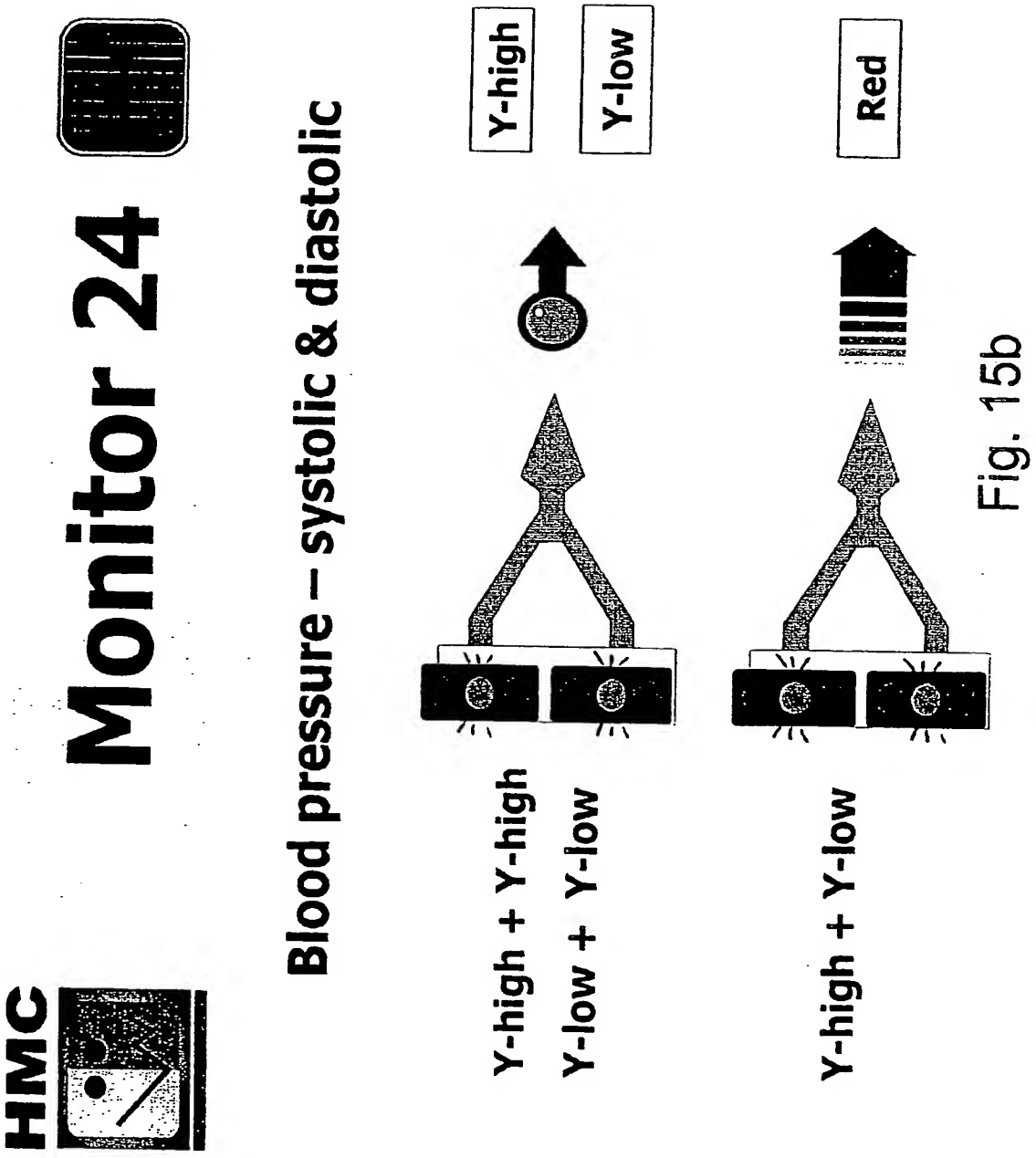


Fig. 15b

OCID: <WO___0130231A2_I_>

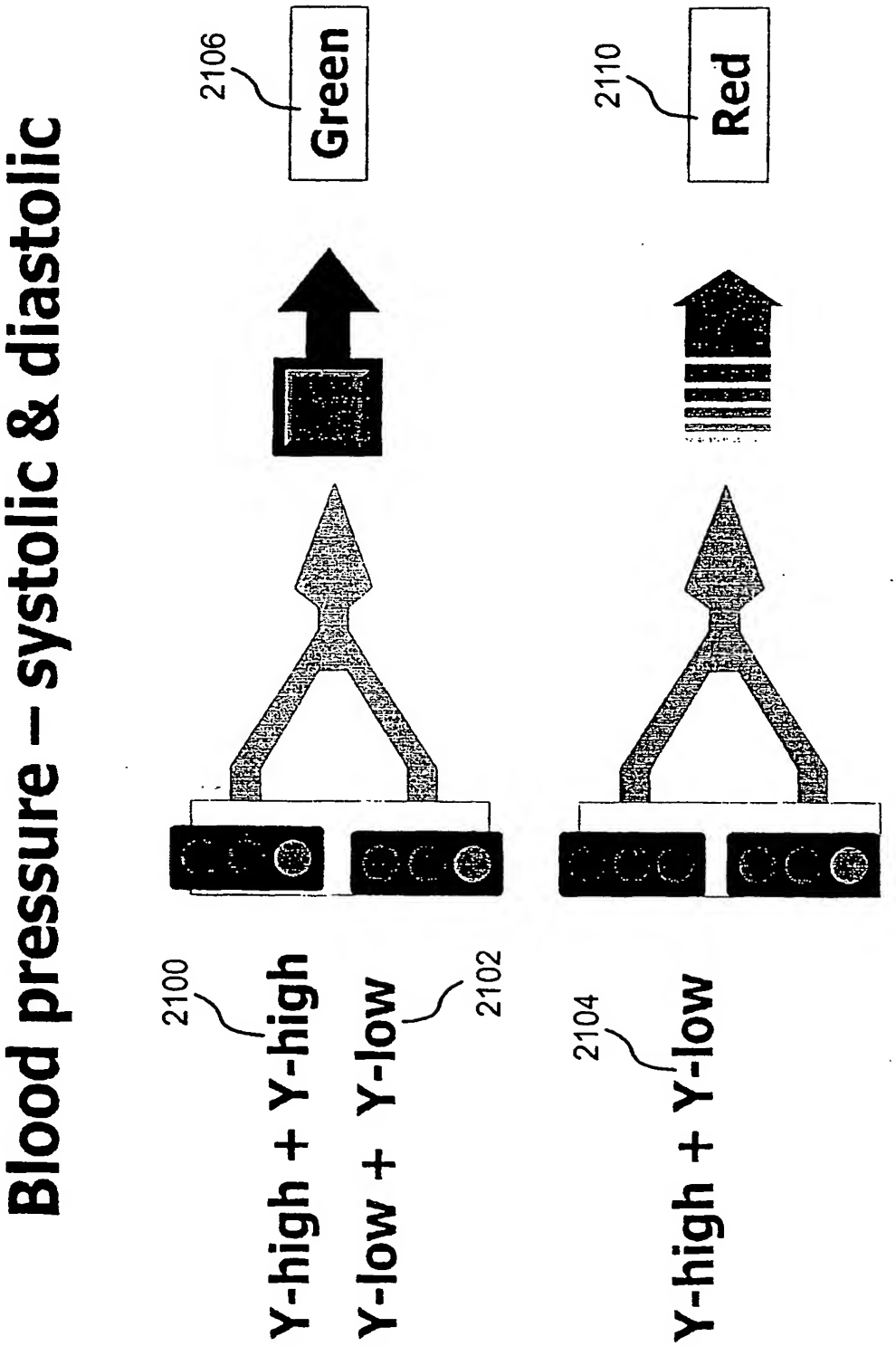


Fig. 16a

DOCID: <WO___0130231A2_I_>

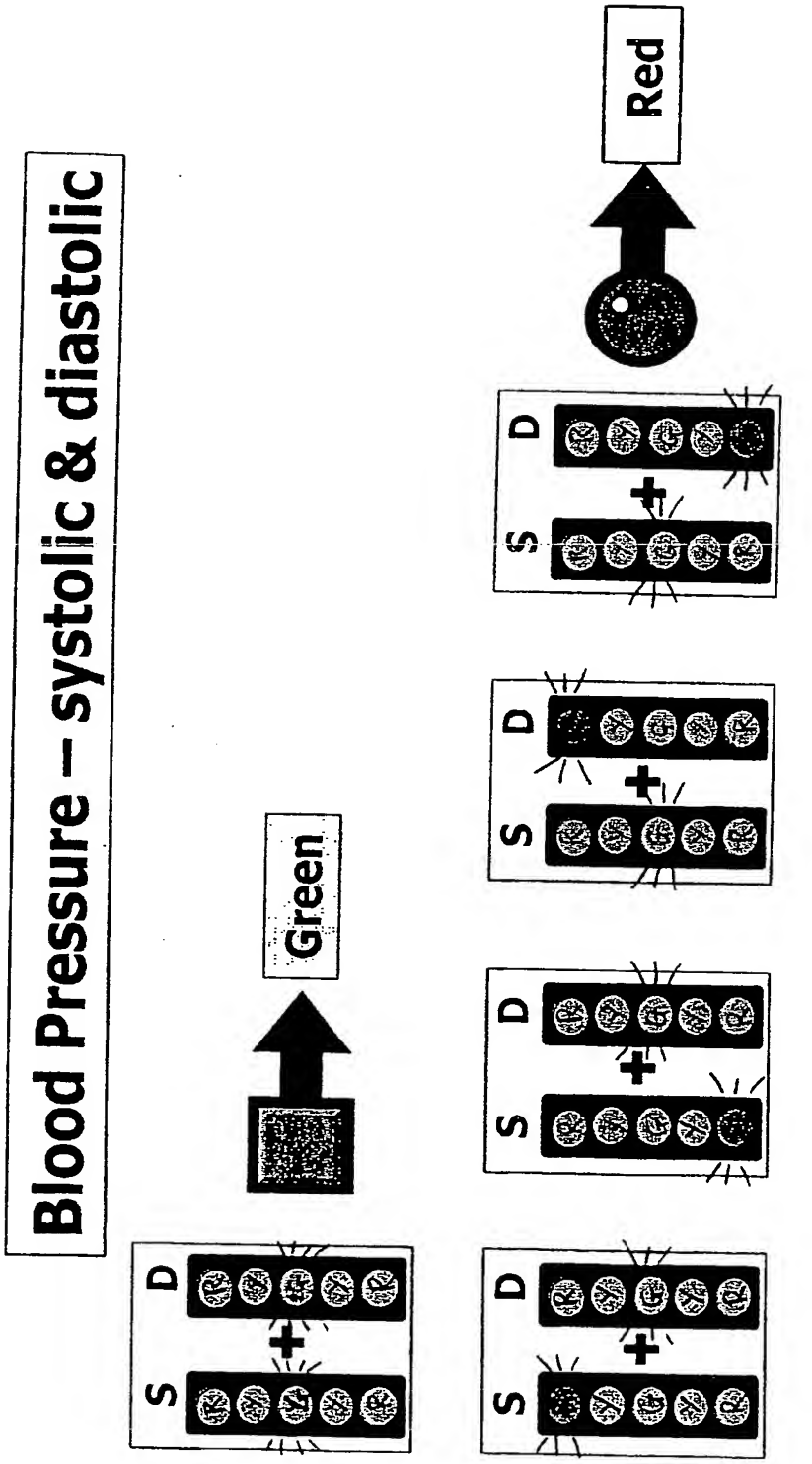


Fig. 16b

XOCID: <WO___0130231A2_I_>

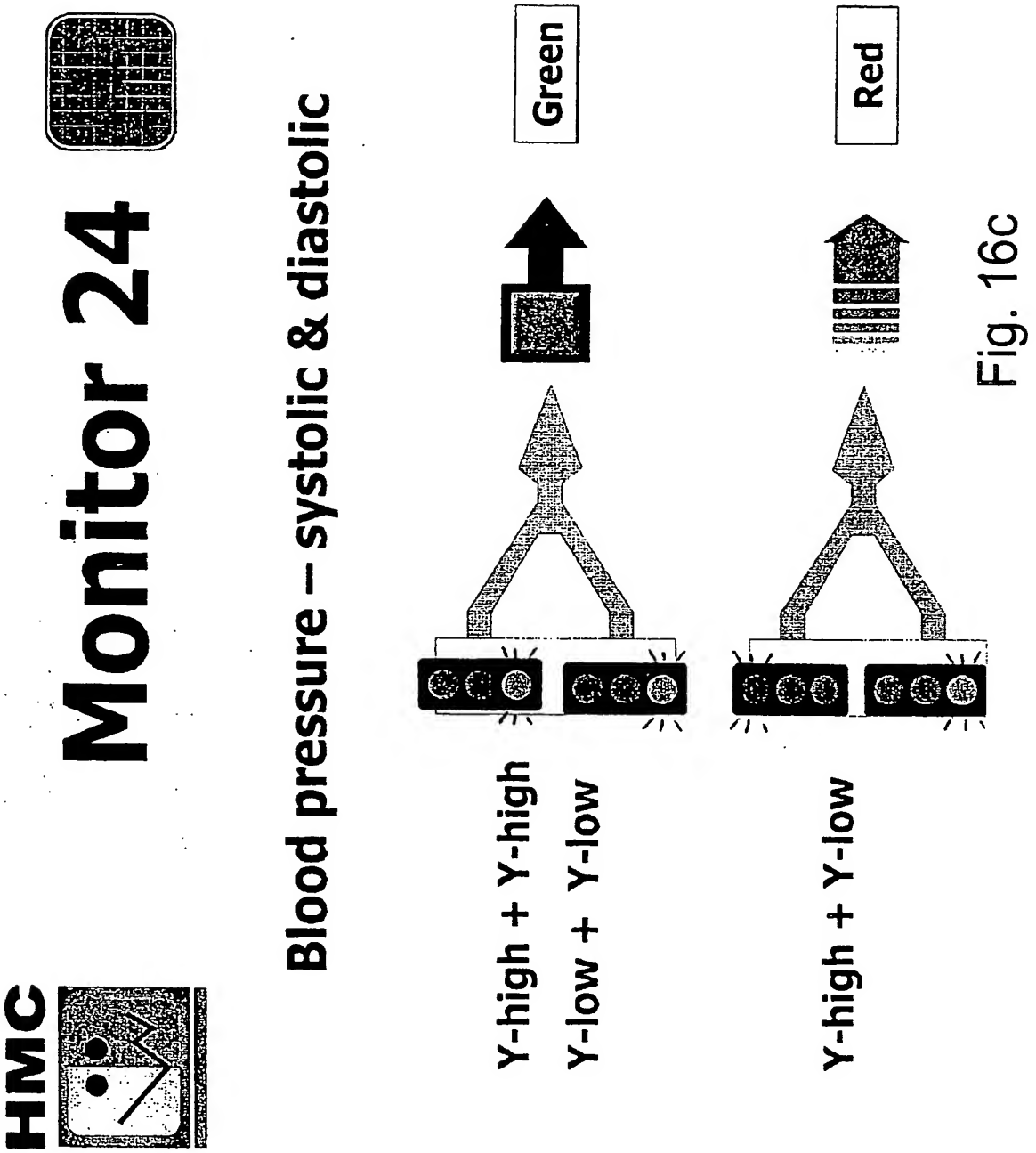


Fig. 16c

DCID: <WO___0130231A2_I_>

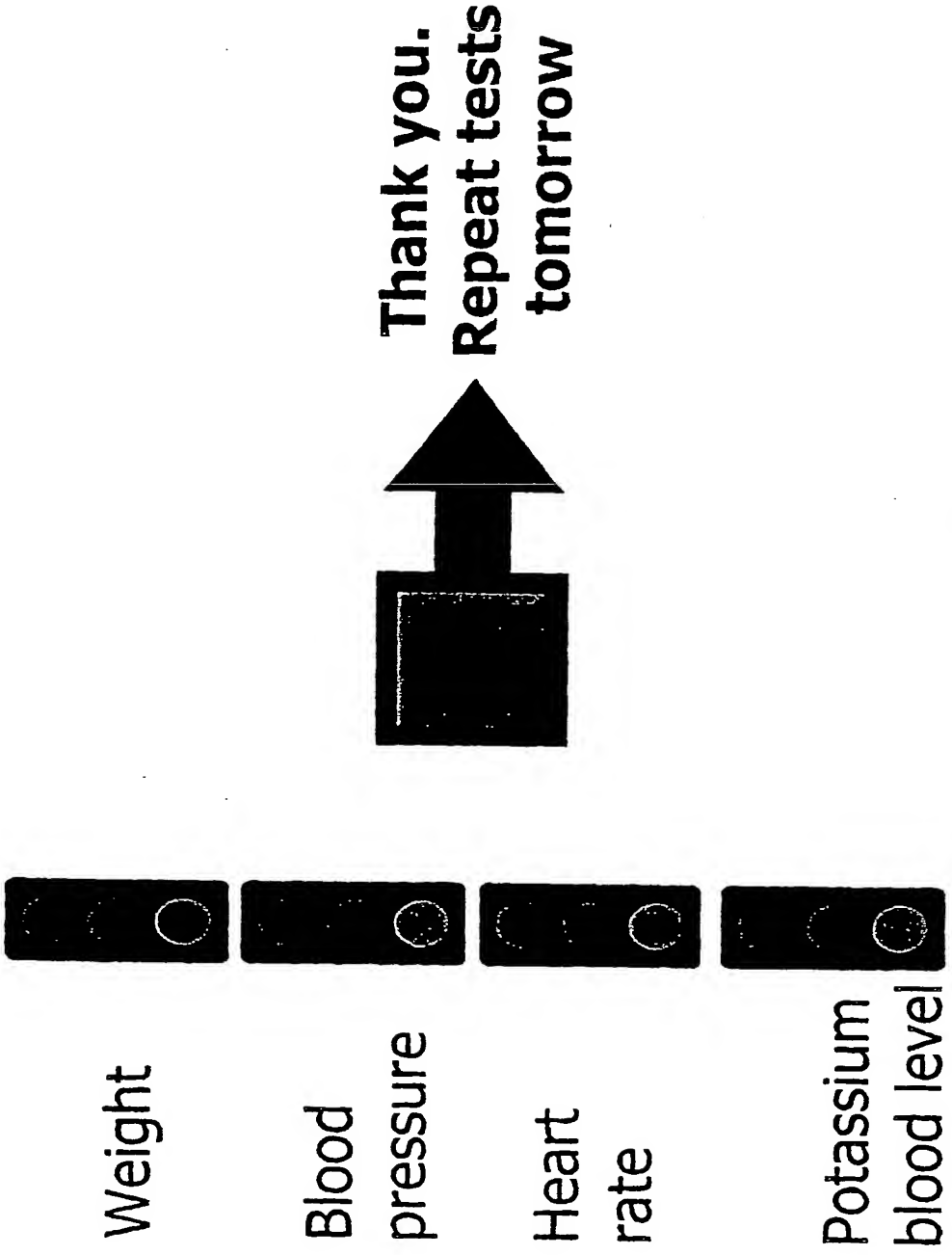


Fig. 17a

OCID: <WO___0130231A2_I_>

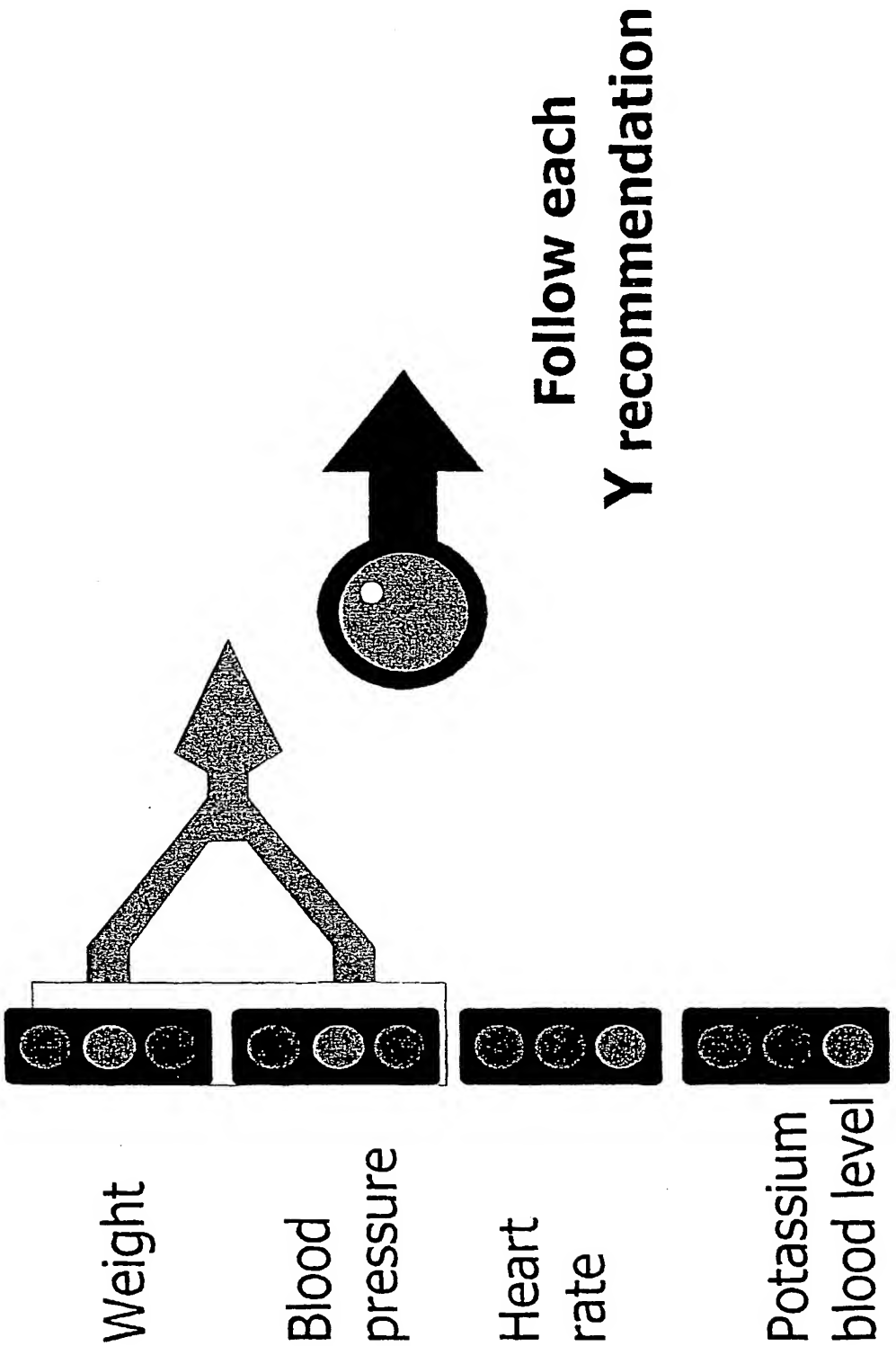


Fig. 17b

)OCID: <WO___0130231A2_I_>

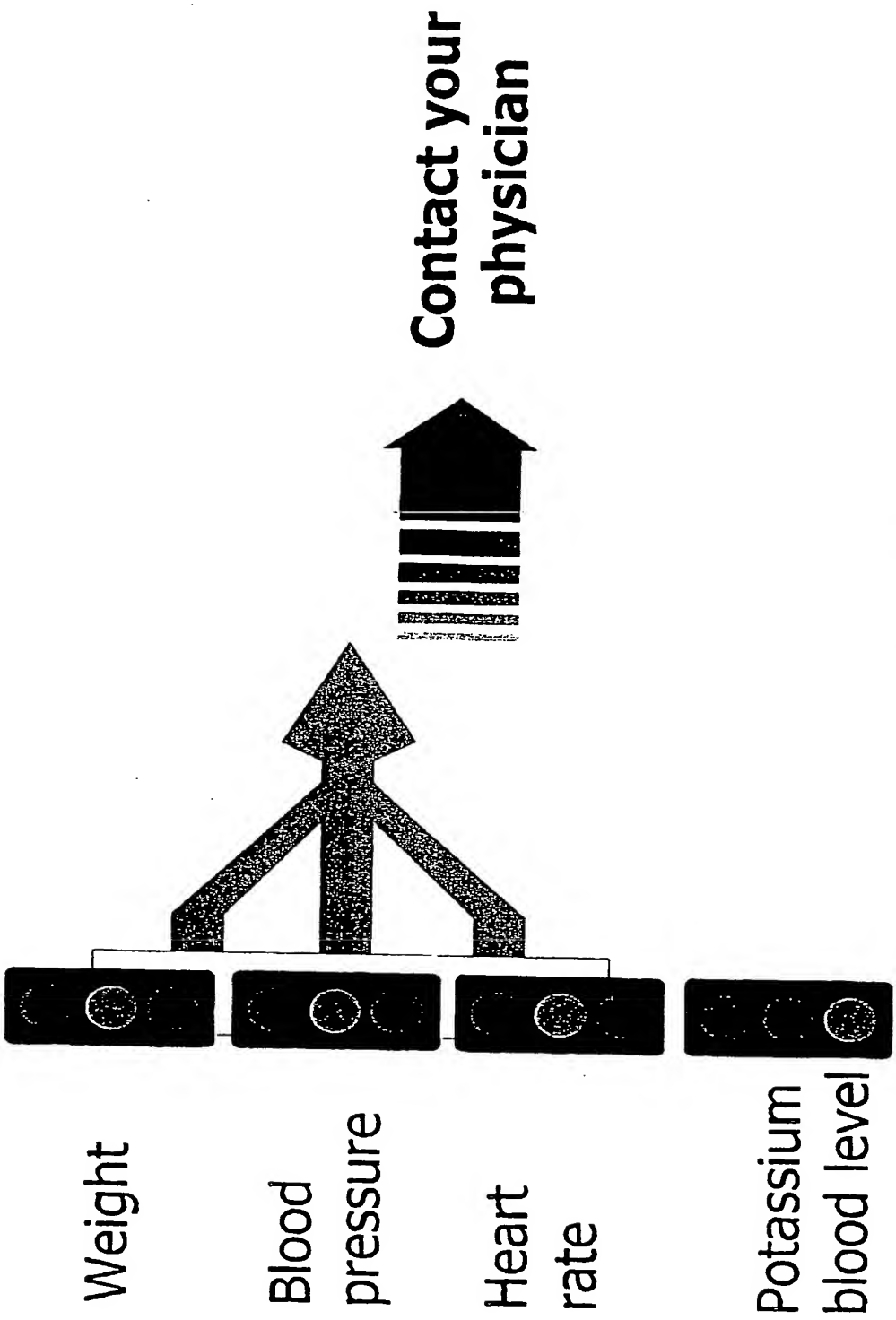


Fig. 17c

XOCID: <WO___0130231A2_I_>

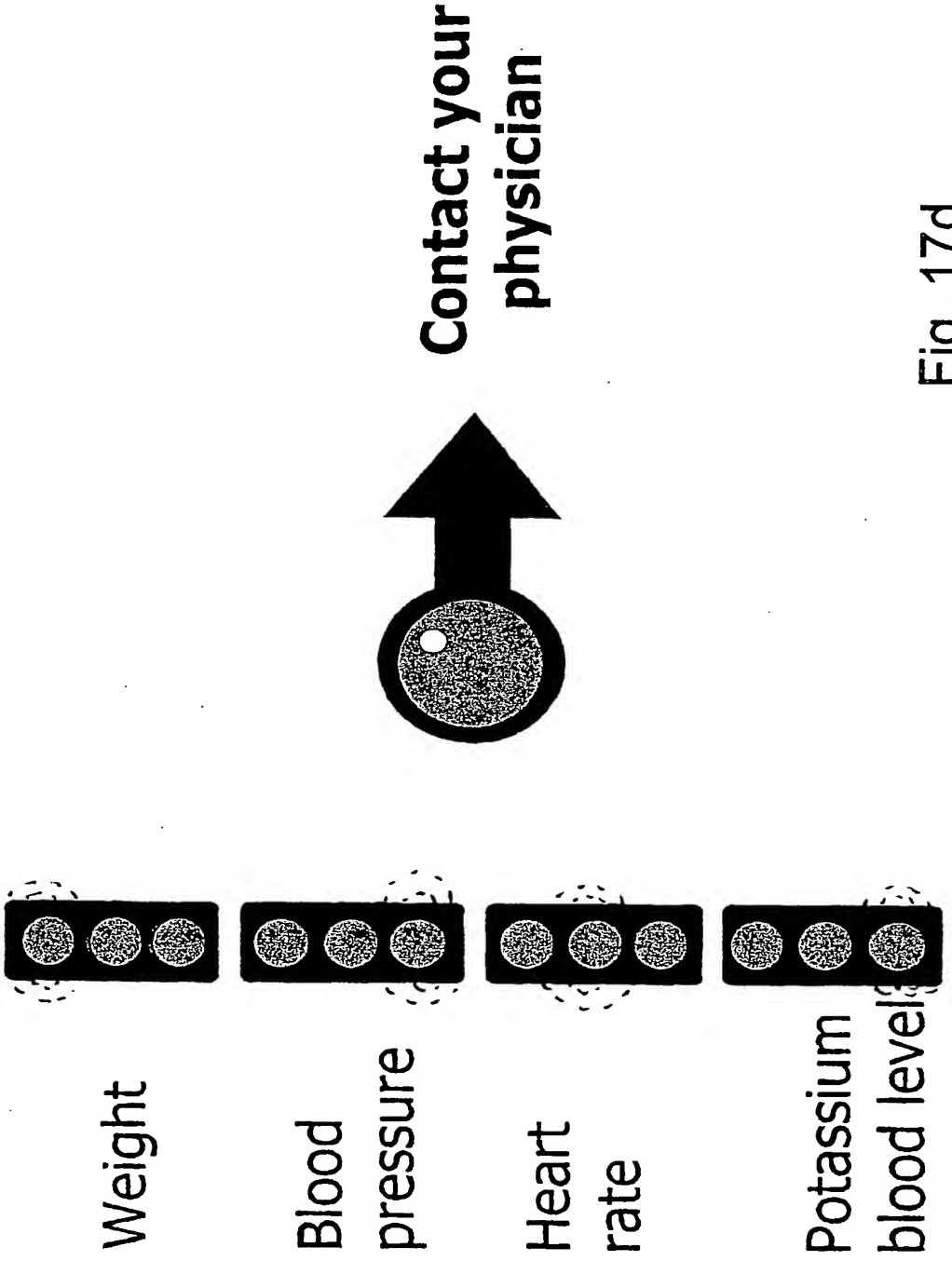
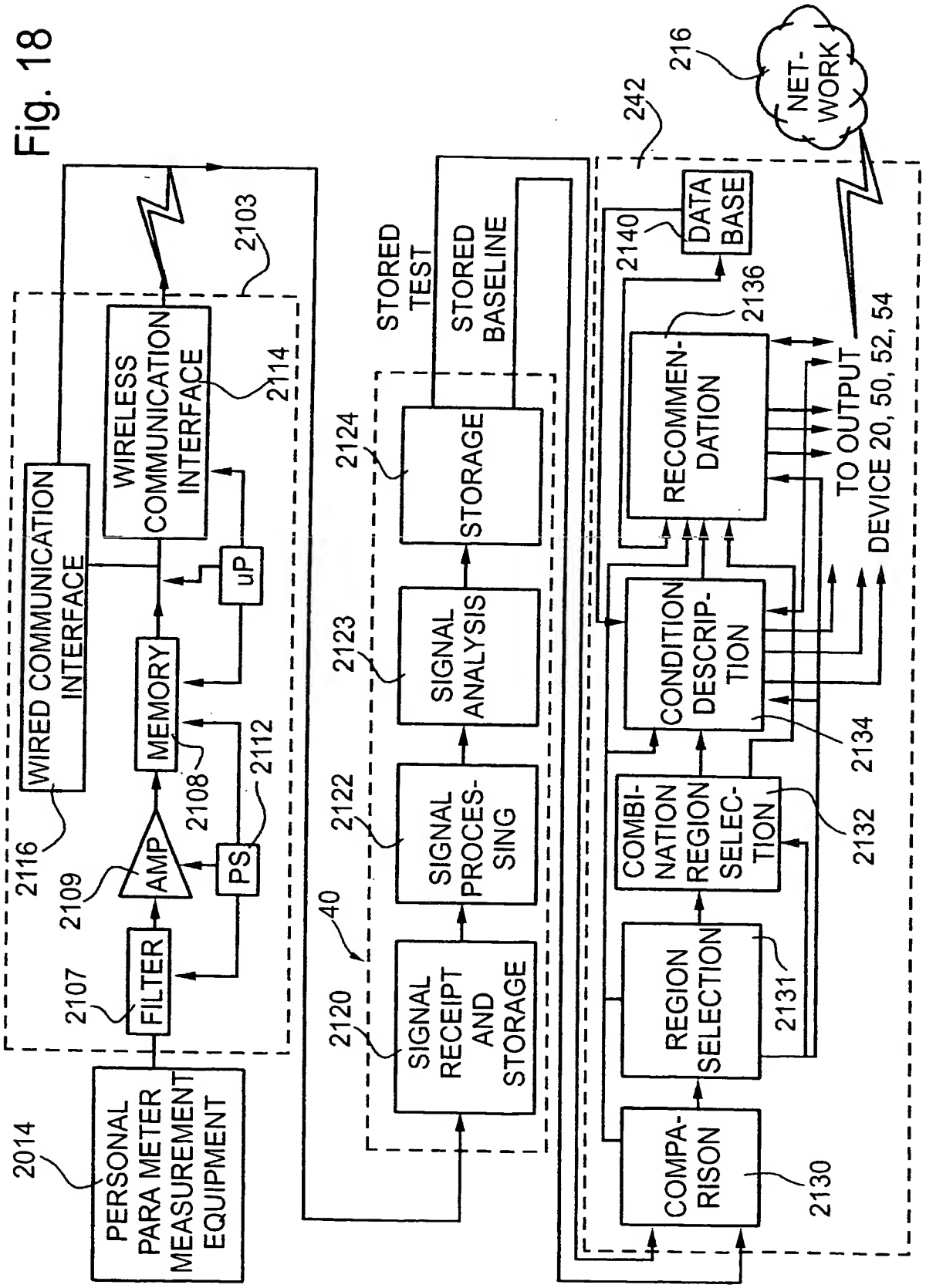


Fig. 17d

DOCID: <WO___0130231A2_I_>

Fig. 18



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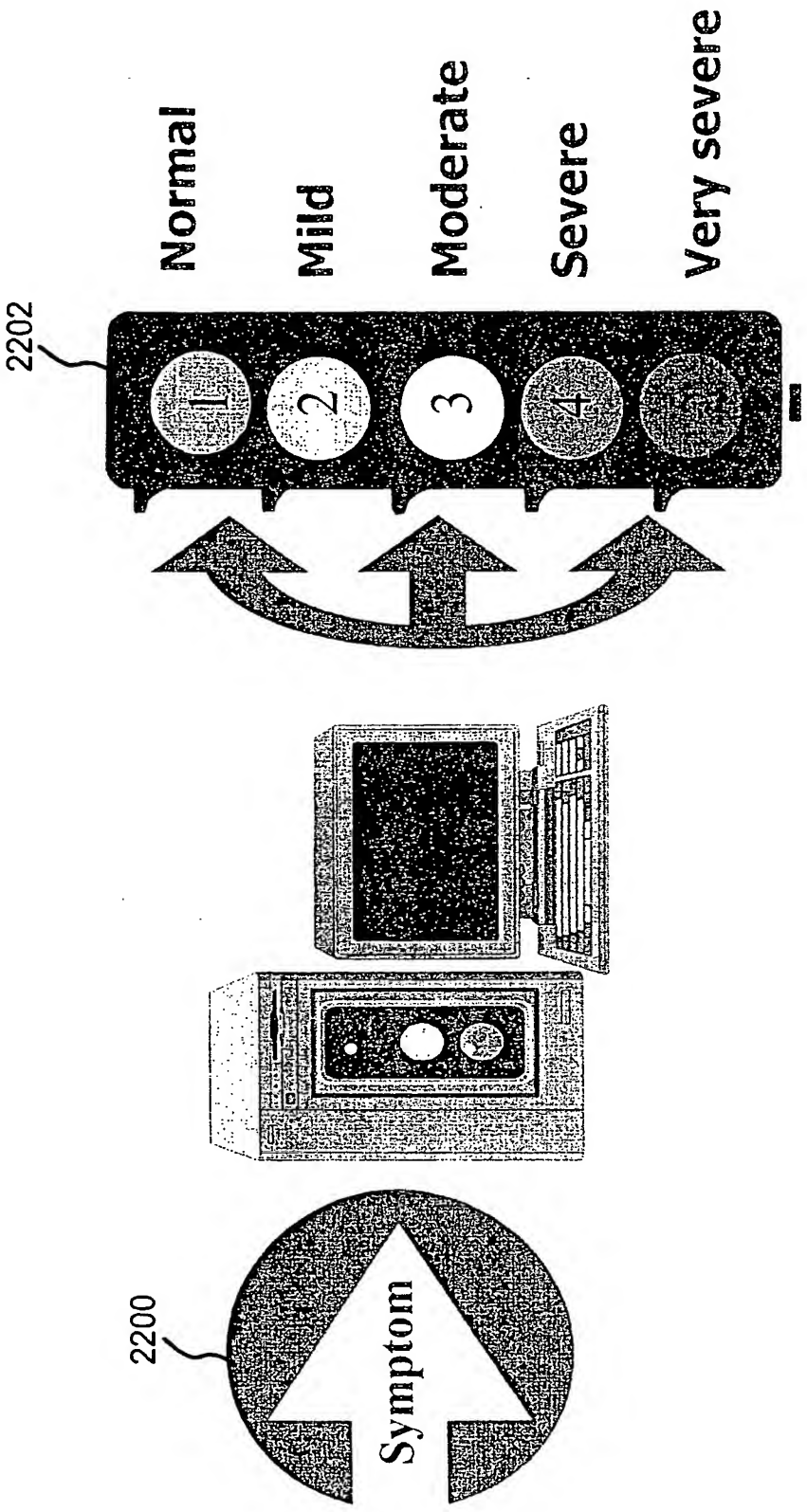

Fig. 19

)OCID: <WO___0130231A2_I_>

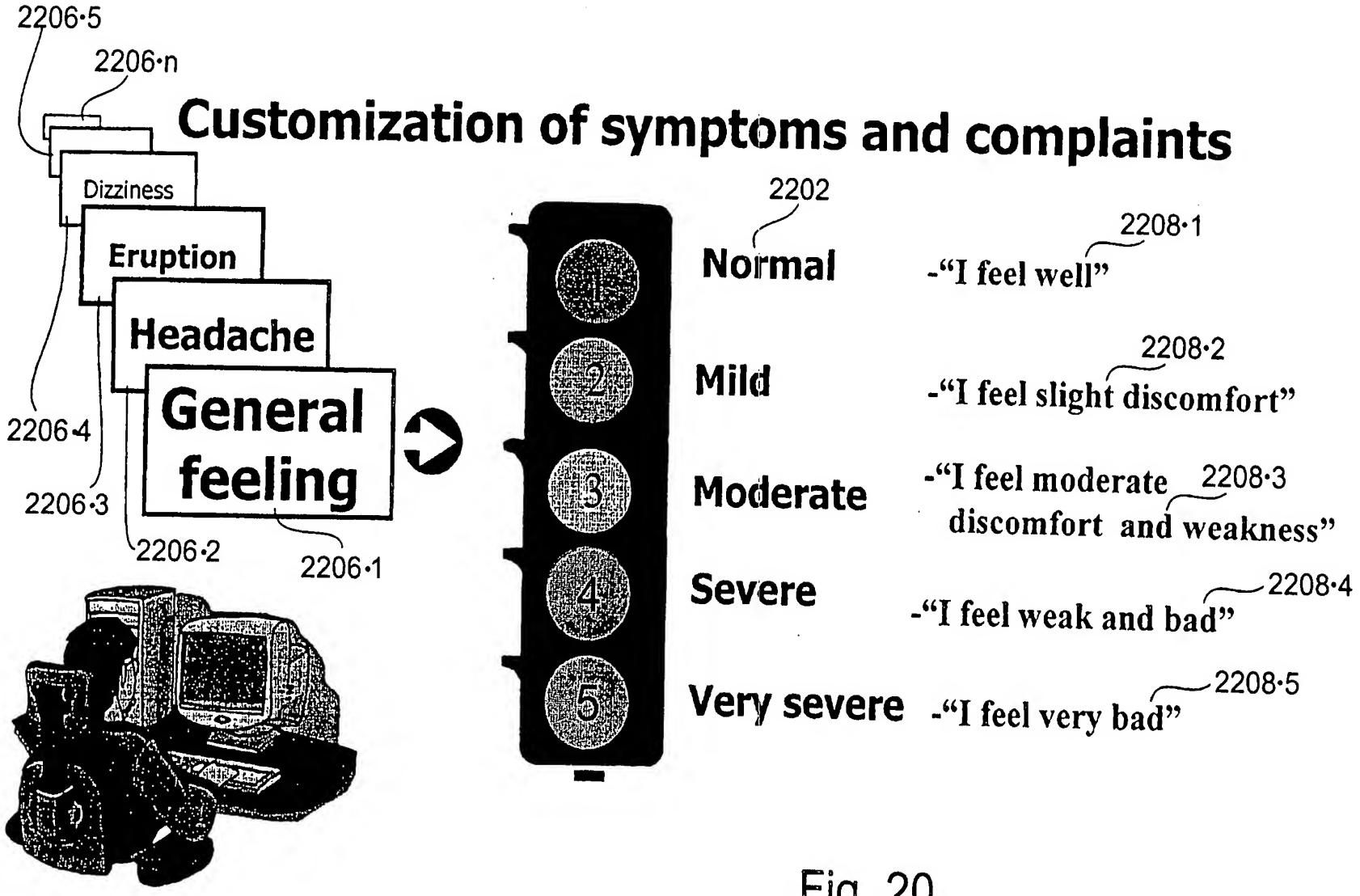
Customization of symptoms and complaints
2206·5
2206·n
Dizziness
Eruption
Headache
General feeling
2206·4
2206·3
2206·2
2206·1
2202
1
2
3
4
5
Normal
2208·1
-"I feel well"
Mild
2208·2
-"I feel slight discomfort"
Moderate
2208·3
-"I feel moderate discomfort and weakness"
Severe
2208·4
-"I feel weak and bad"
Very severe
2208·5
-"I feel very bad"

Fig. 20

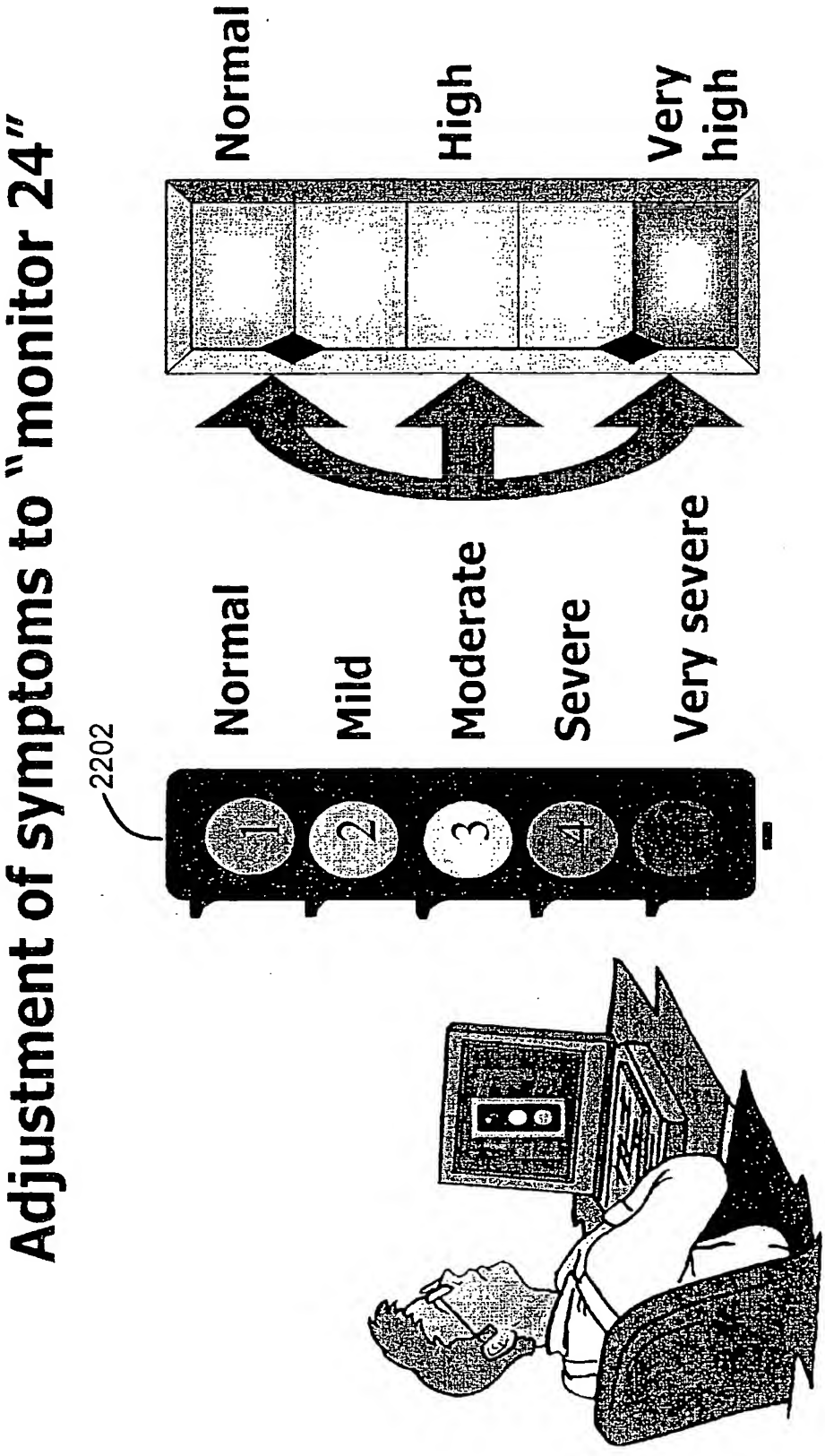

Fig. 21

DOCID: <WO___0130231A2_I_>

Fig. 22

IOCID: <WO___0130231A2_I_>

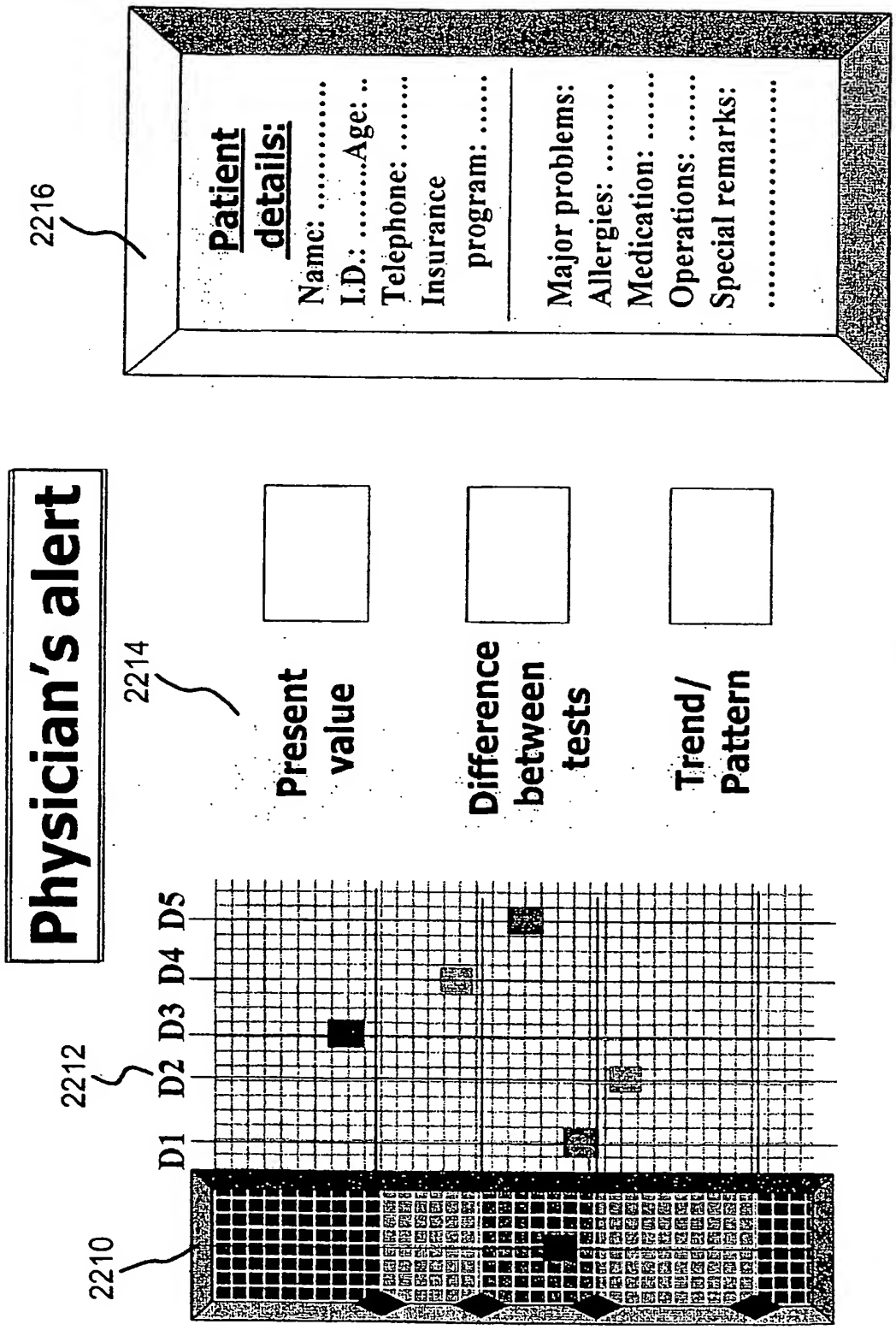

Fig. 23

OCID: <WO___0130231A2_I_>

Patient's notification

Patient receives reaction classified into three categories:

Red:
- Contact your physician A.S.A.P.
- Go to emergency room.

Yellow:
- Specific action item, according to the specific patient and medical condition.

Green:
- No change. Repeat test according to normal scheduling.

Fig. 24

OCID: <WO __0130231A2_I_>

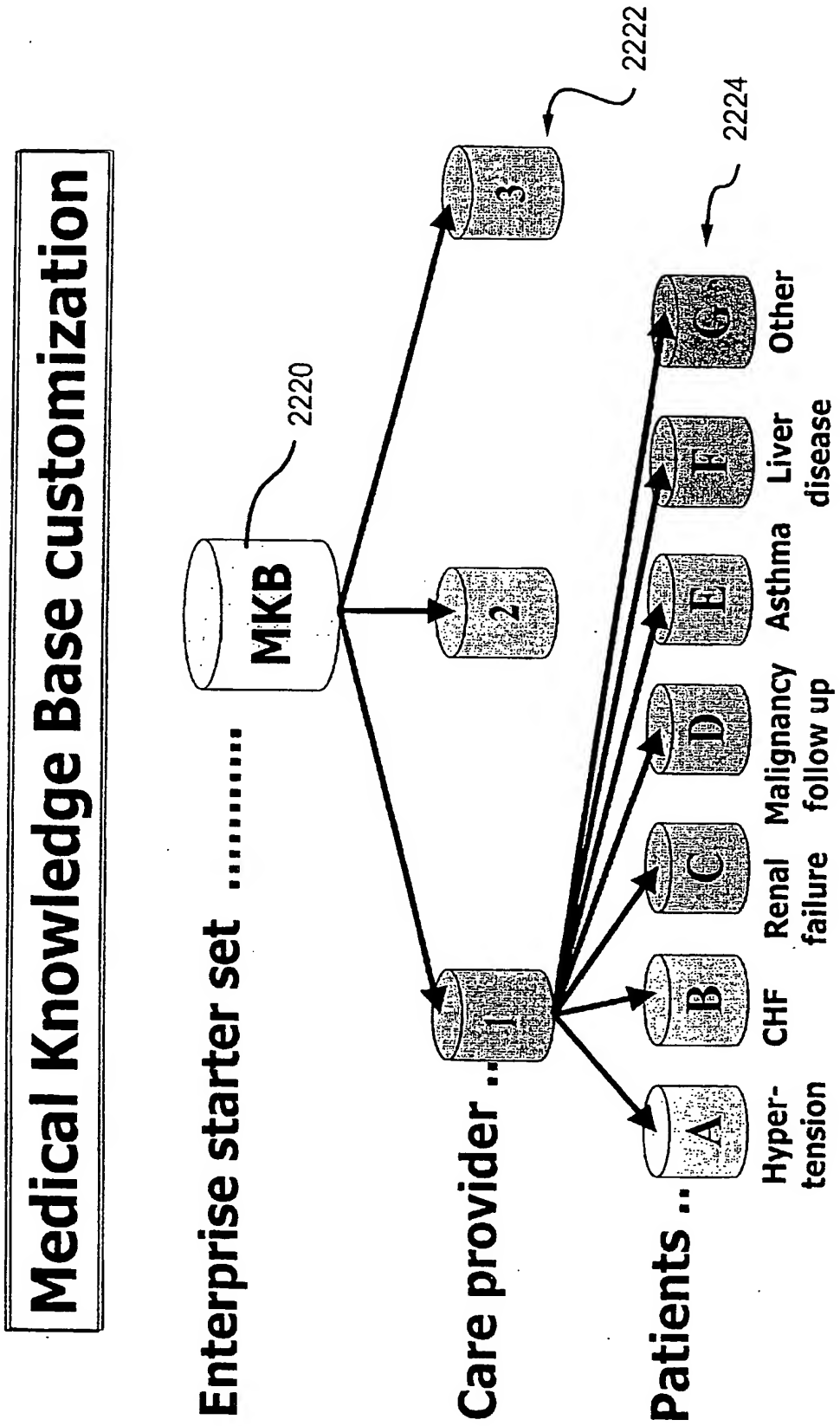

Fig. 25

OCID: <WO___0130231A2_I_>

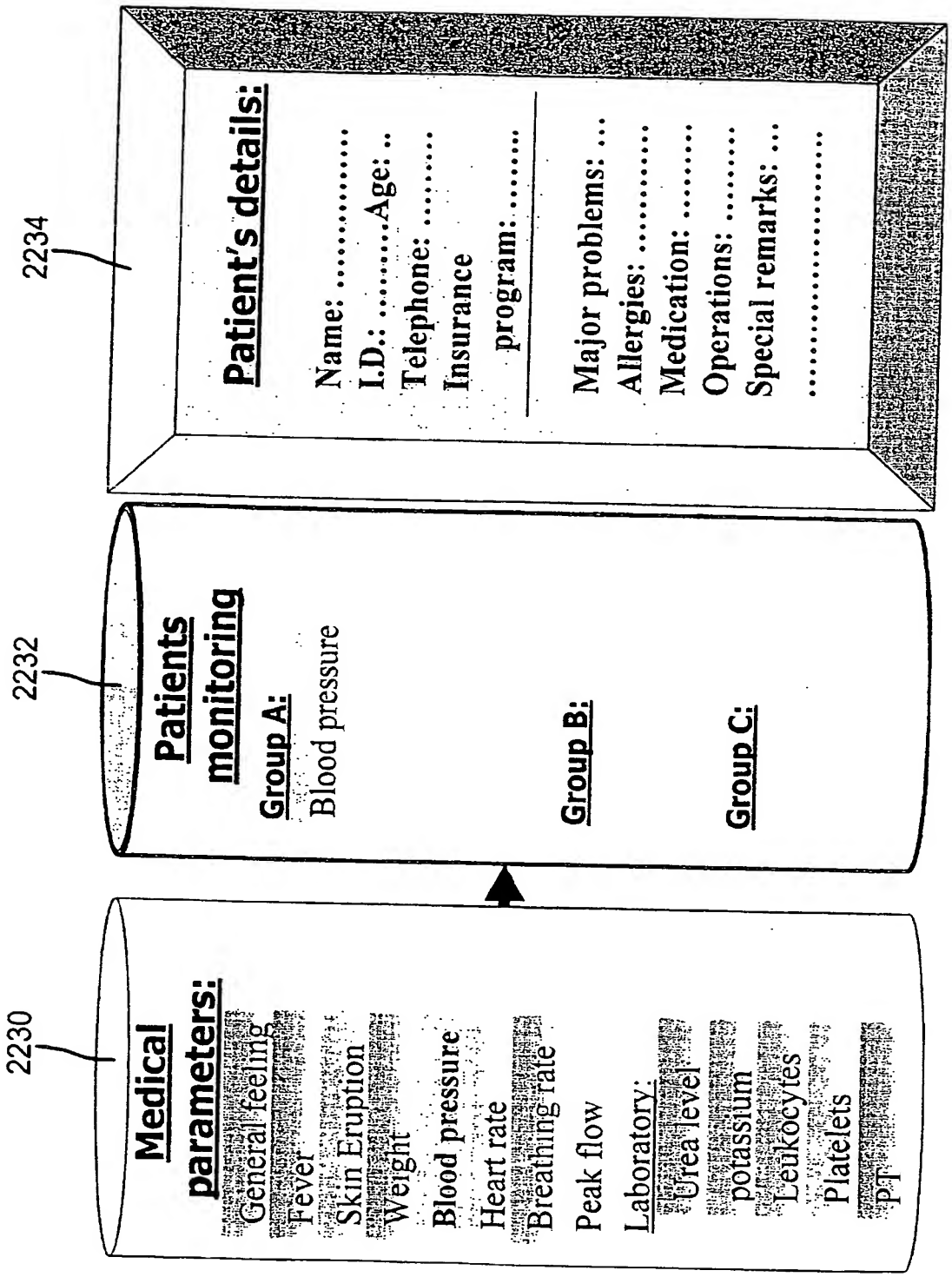

Fig. 26

OCID: <WO___0130231A2_I_>

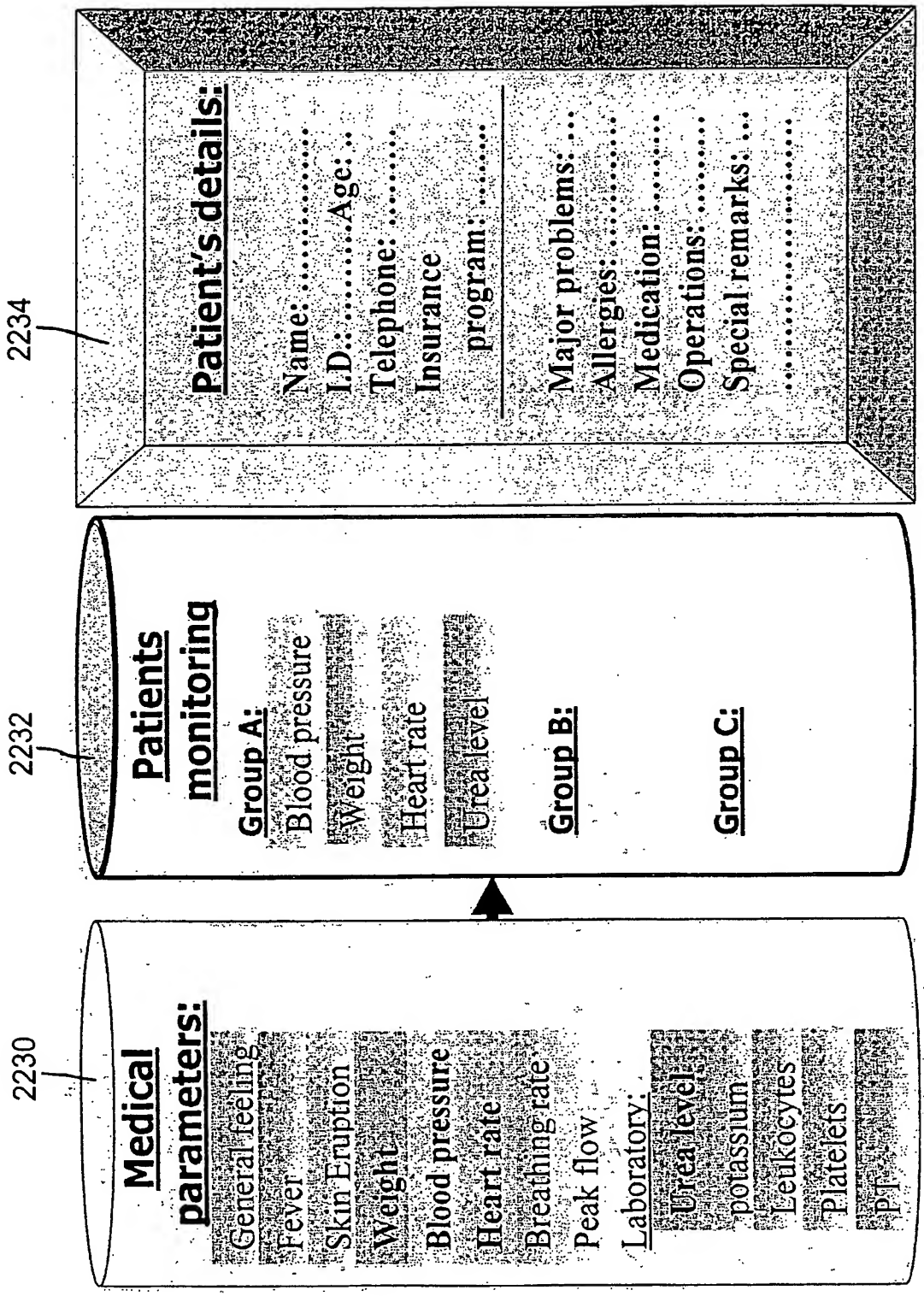

Fig. 27

)OCID: <WO___0130231A2_I_>

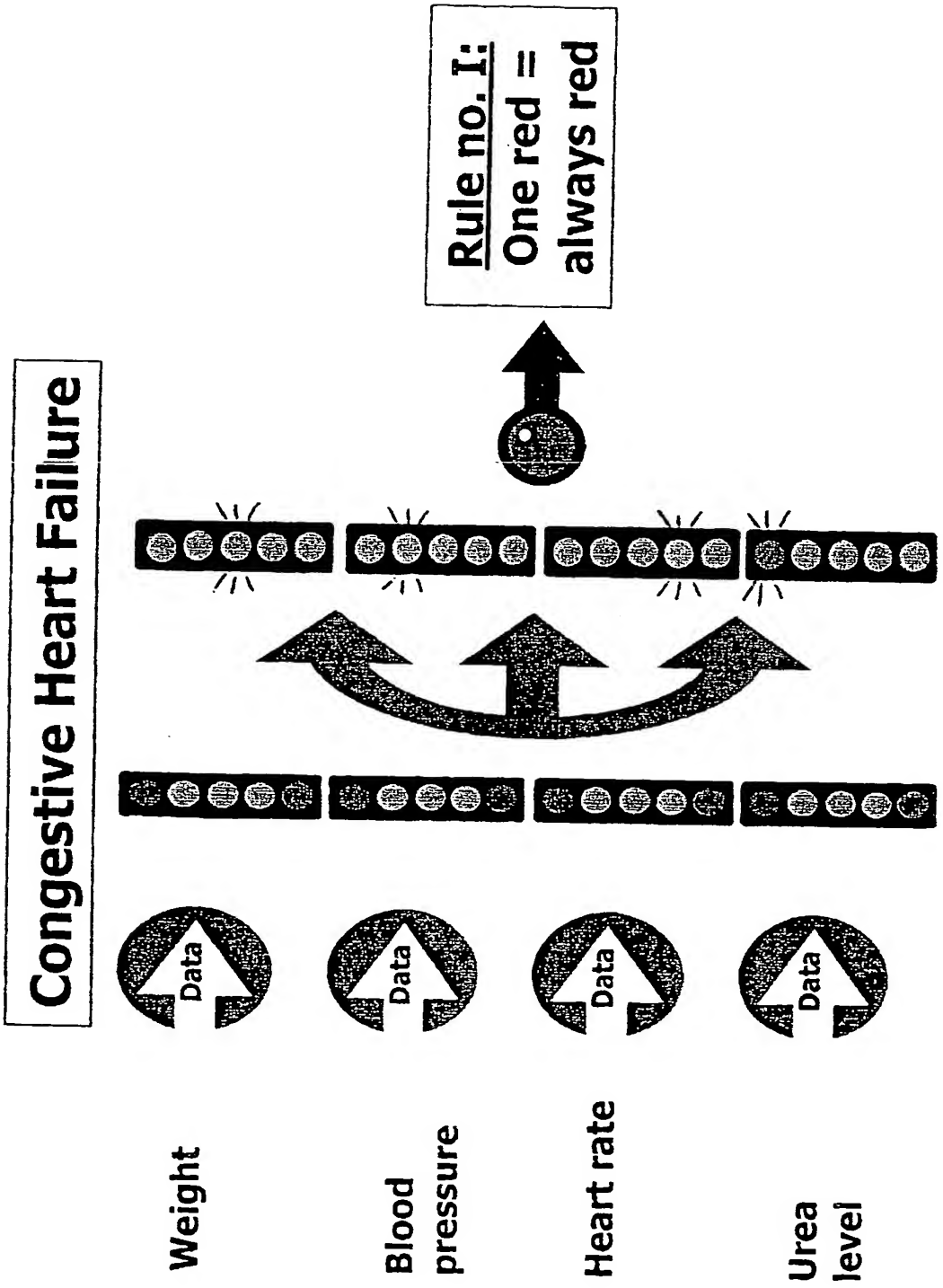

Fig. 28a

XOCID: <WO___0130231A2_I_>

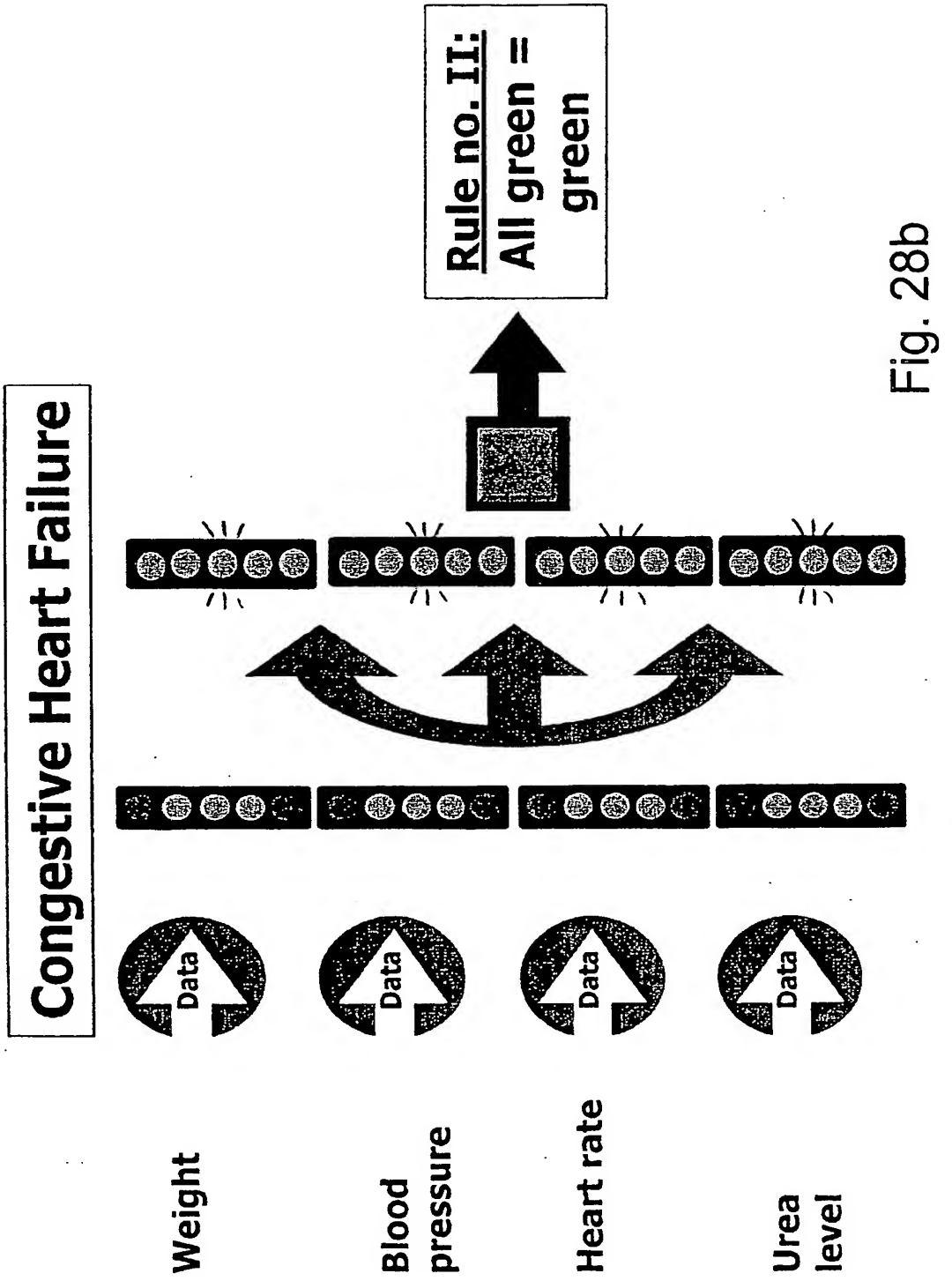

Fig. 28b

DOCID: <WO___0130231A2_I_>

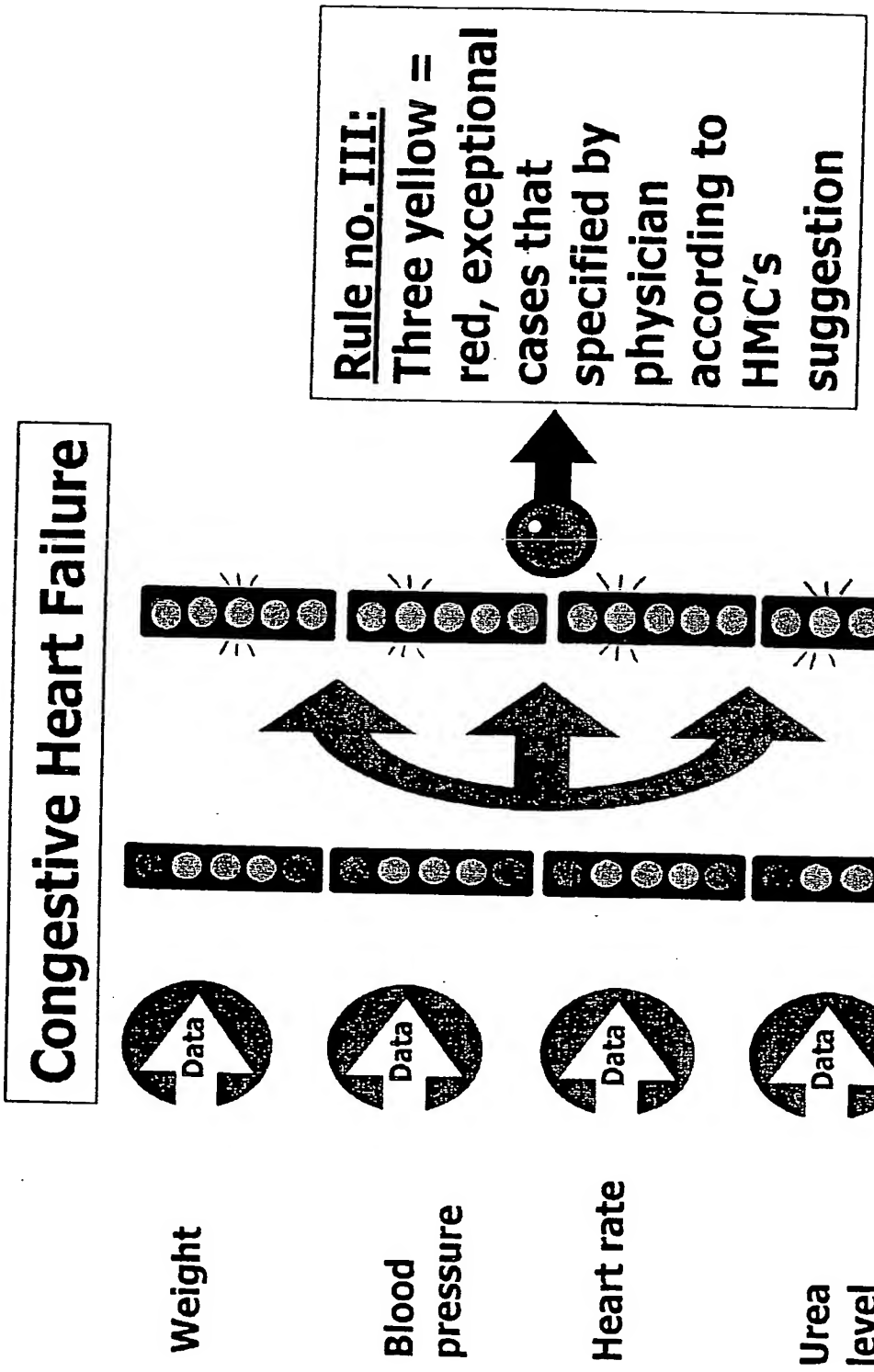

Fig. 28c

:DOCID: <WO___0130231A2_I_>

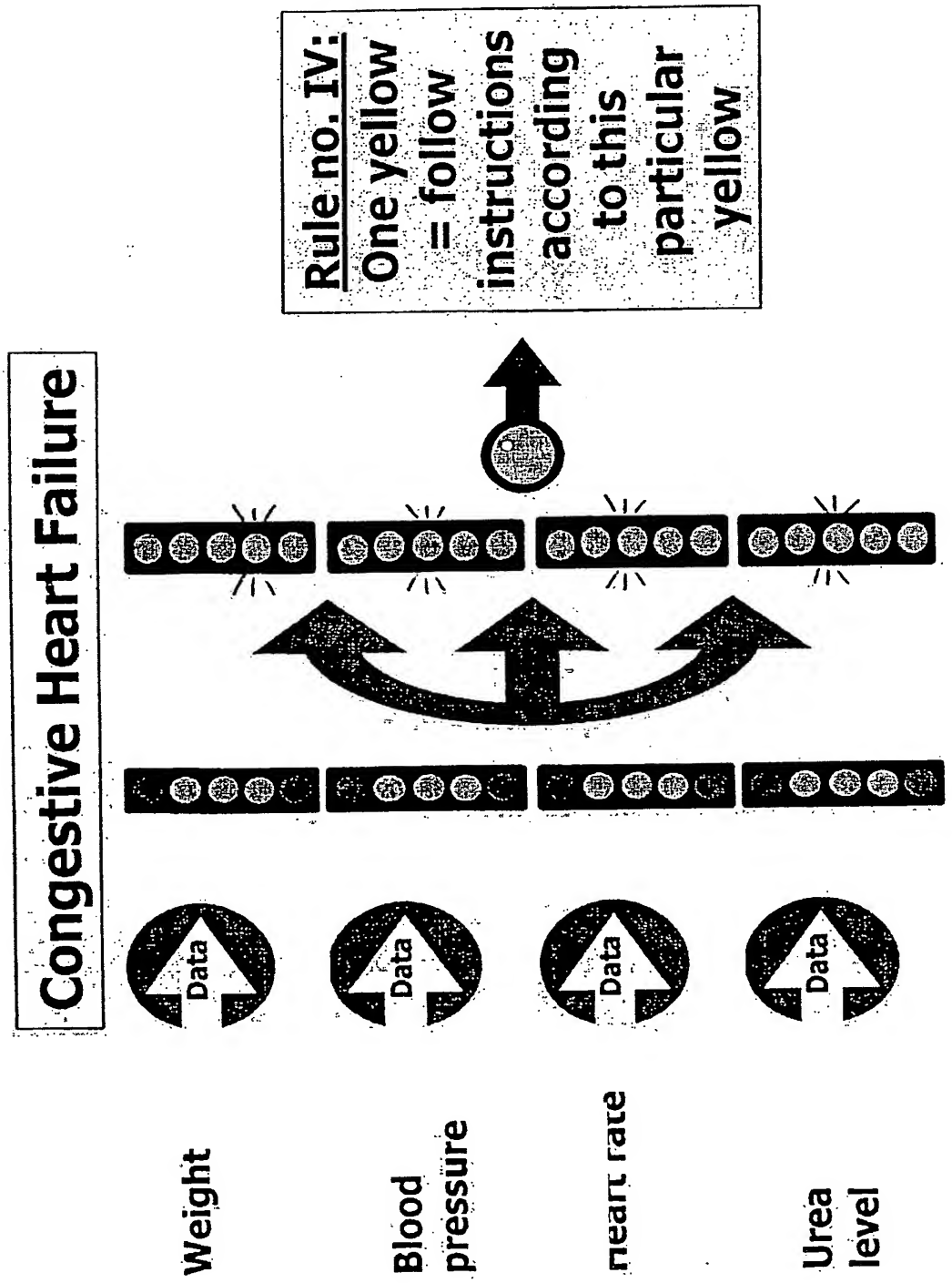

Fig. 28d

)OCID: <WO___0130231A2_I_>

Fig. 29a

DOCID: <WO___0130231A2_I_>

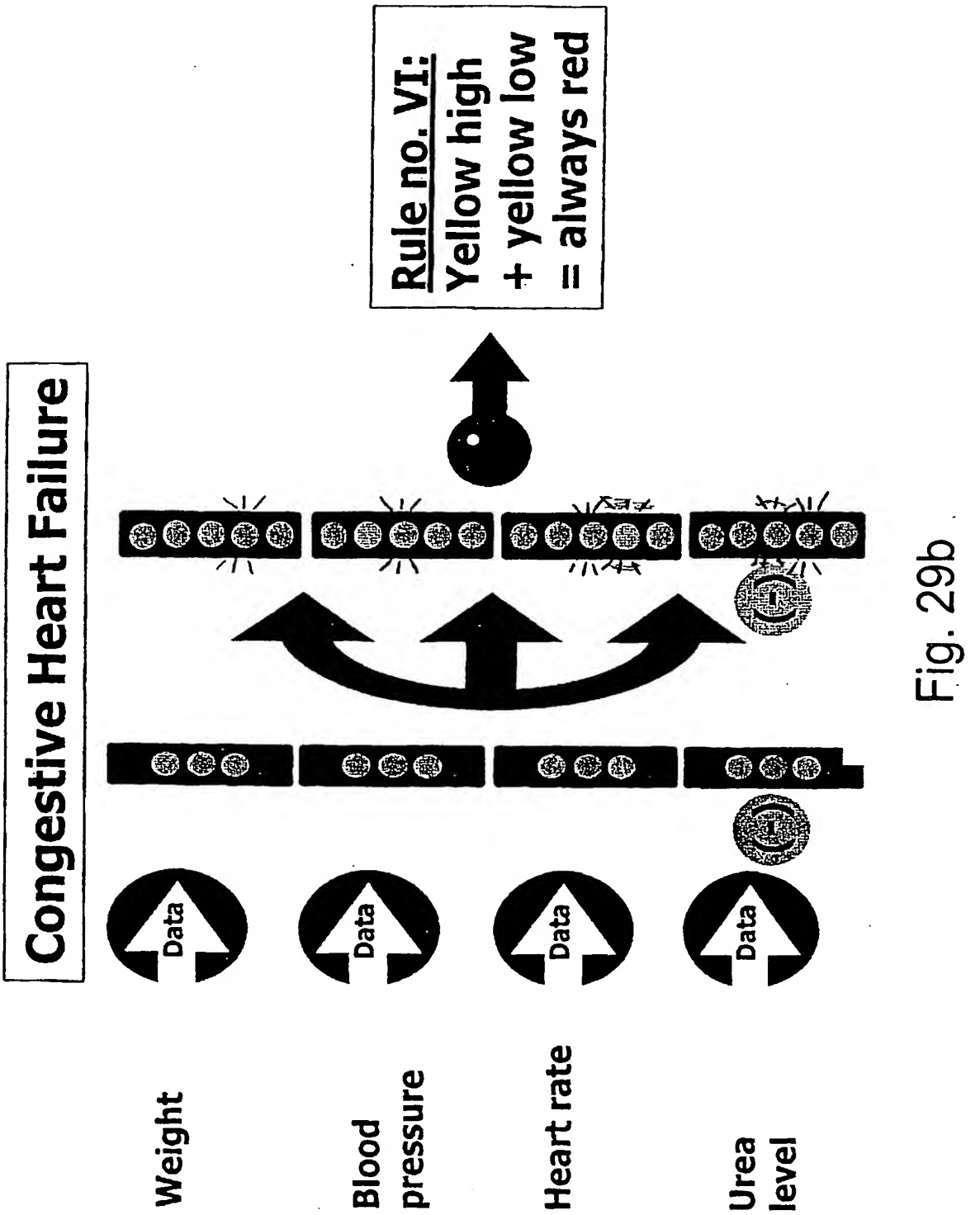

Fig. 29b

OCID: <WO___0130231A2_I_>

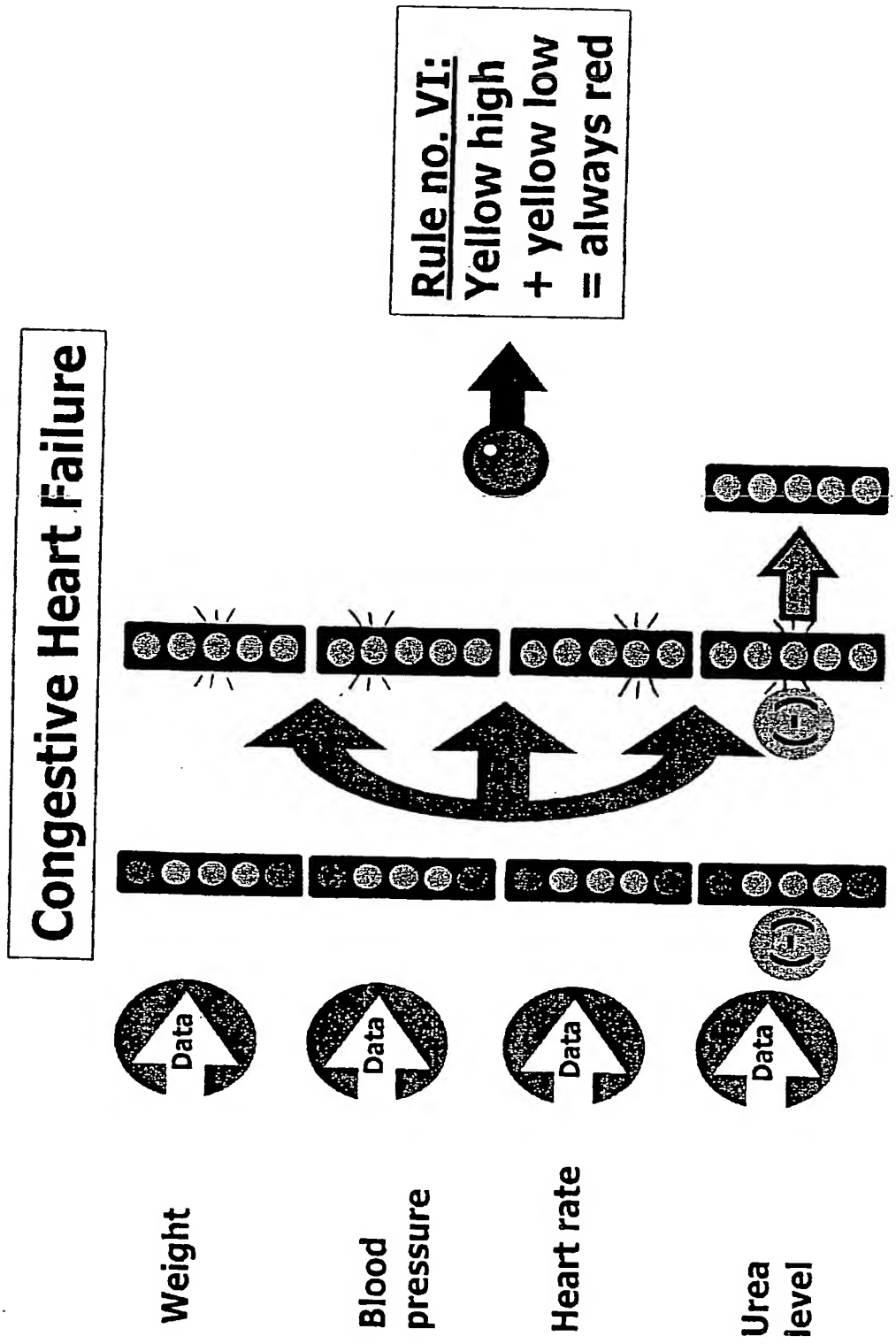

Fig. 29c

IOCID: <WO___0130231A2_I_>

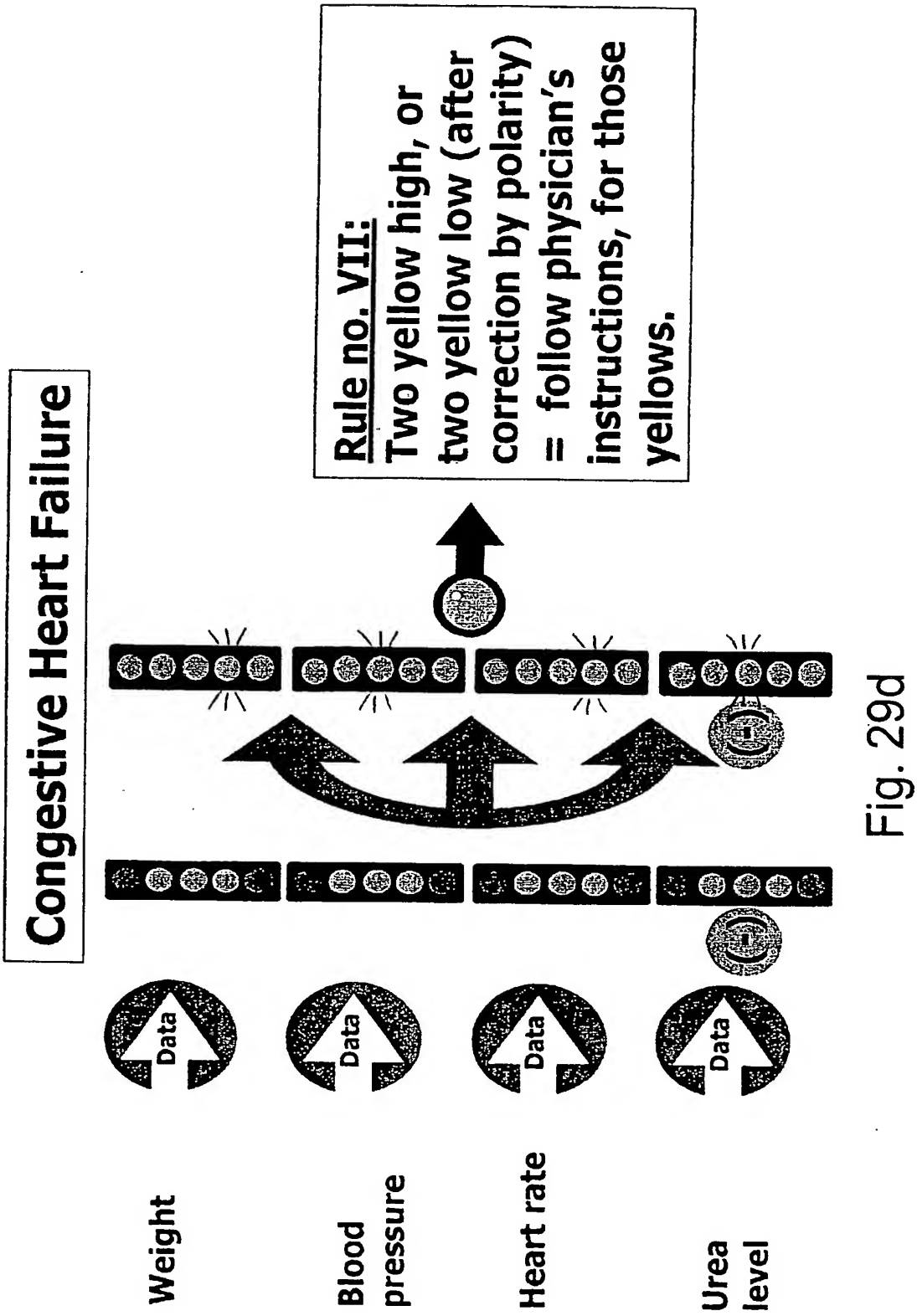

Fig. 29d

)OCID: <WO___0130231A2_I_>

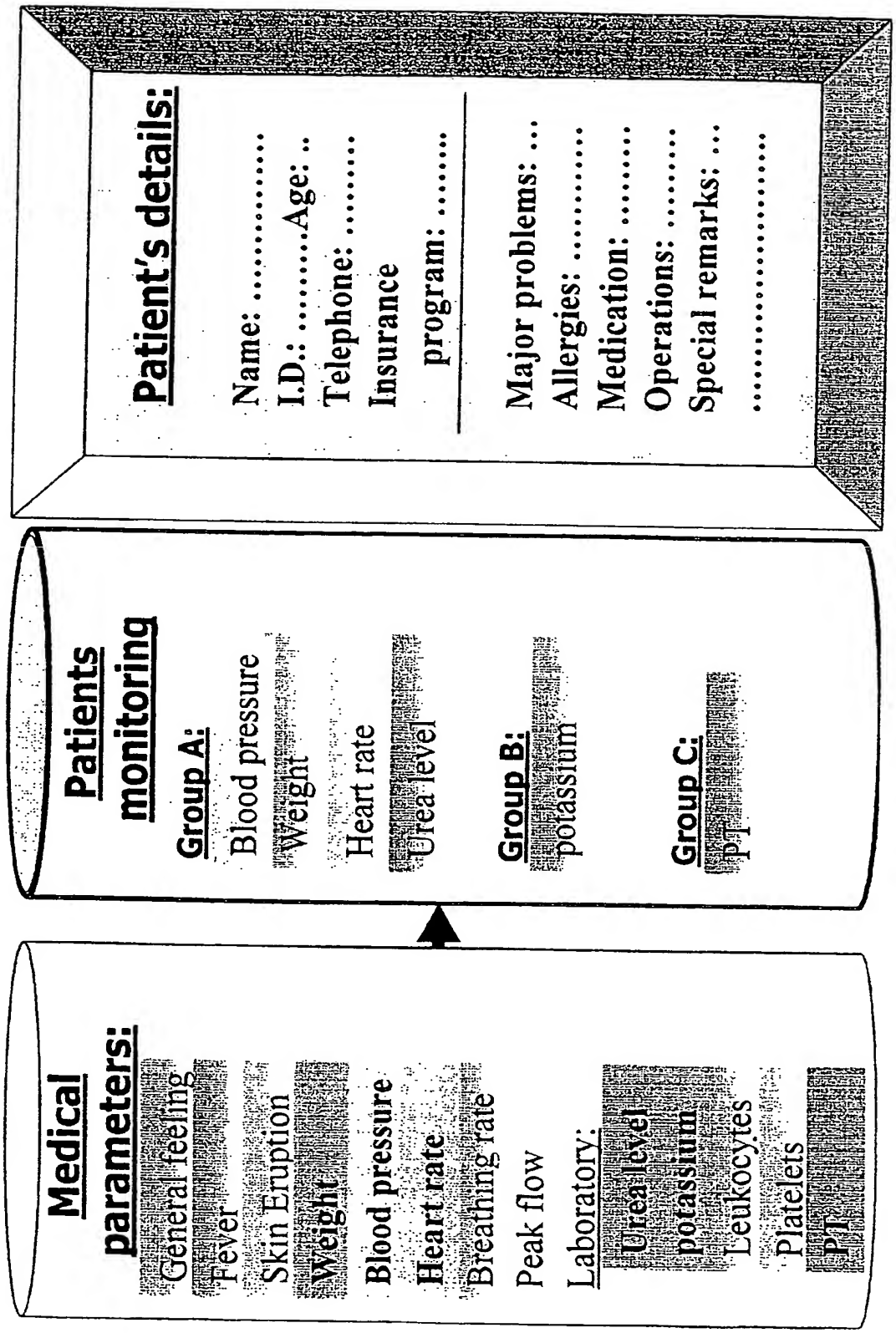

Fig. 30

OCID: <WO___0130231A2_I_>

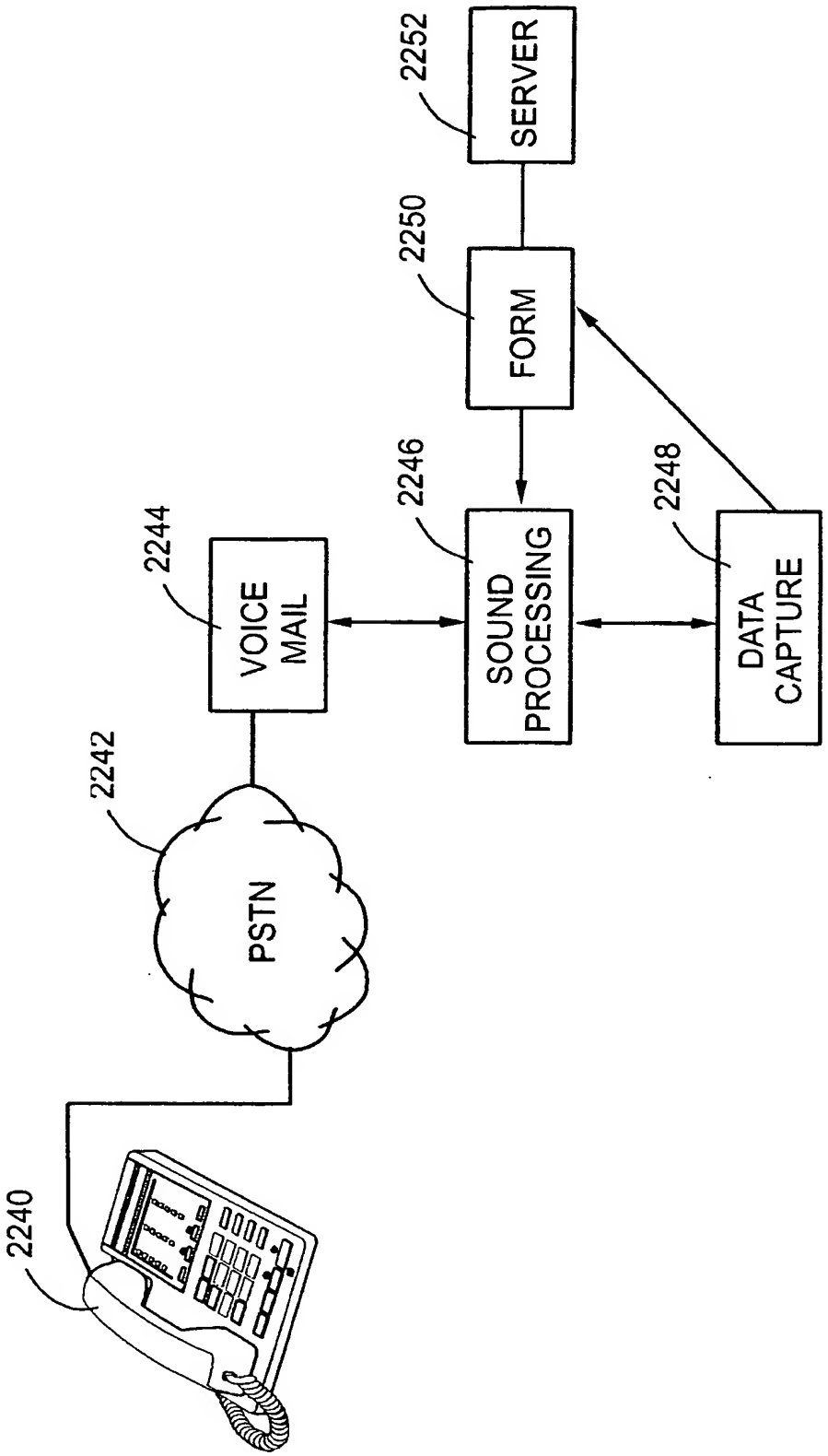

Fig. 31

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(71) Applicant *(for all designated States except US)*: **HOME-MEDICINE (USA), INC.** [US/US]; c/o Pepper Hamilton LLP, 1201 Market Street, Suite 1600, Wilmington, DE 19801 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **SAREL, Oded** [IL/IL]; Tel-Zur Street 37, 40 500 Even Yehuda (IL).

(74) Agent: **G. E. EHRLICH (1995) LTD.**; Bezalel Street 28, 52 521 Ramat Gan (IL).

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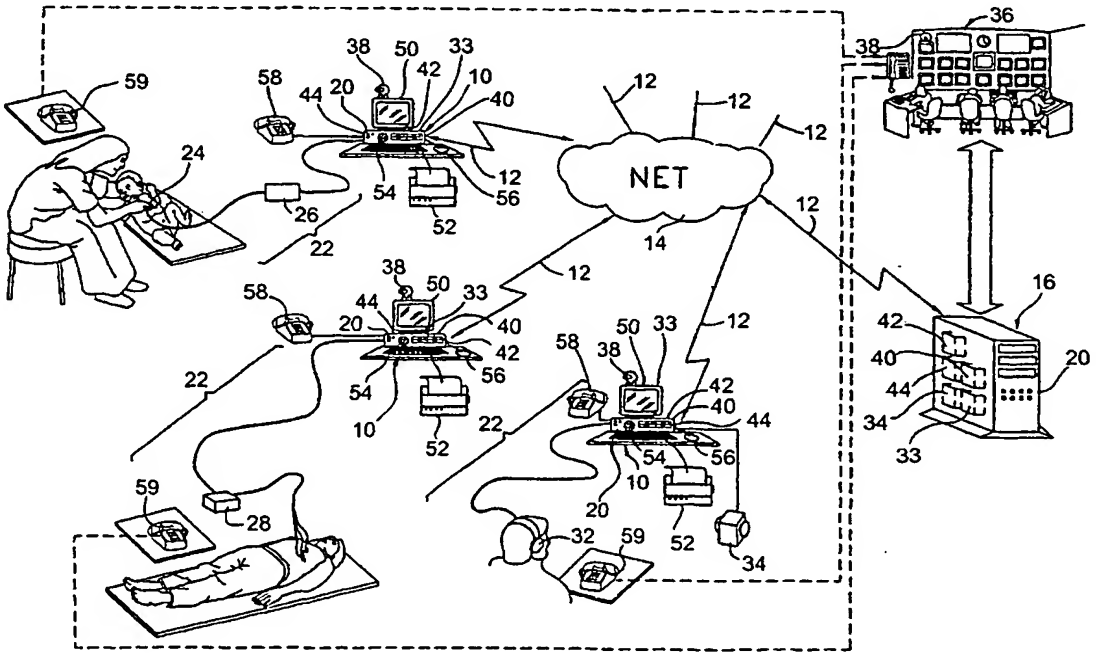
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PARAMETER SENSING AND EVALUATION SYSTEM



(57) Abstract: A parameter evaluation system (20) for a patient in a network (12) with doctor.

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INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

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US CL :600/300

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/300-301; 128/903-904, 920-925; 705/2-3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 6113540 A (Iliff) 05 SEPTEMBER 2000, see entire document	1-93
Y	US 6080106 A (Lloyd et al.) 27 JUNE 2000, see entire document	1, 42, 48, 49, 51, 52, 56, 69, 74, 79, 81
Y	US 5211564 A (Martinez et al.) 18 MAY 1993, see entire document	1-93
Y	US 5283856 A (Gross et al.) 01 FEBRUARY 1994, see entire document	1-93

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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